UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.

Defendants.

Case: 1:20–mc–00023
Assigned To : Sullivan, Emmet G.
Assign. Date : 4/10/2020
Misc. No.: Description: Misc.

[S.D.N.Y. Case No. 1:17-cv-00124-LLS]

MOTION TO COMPEL PRODUCTION OF DOCUMENTS PURSUANT TO FED. R. CIV. P. 45

Plaintiff the Federal Trade Commission (FTC) moves pursuant to Federal Rule 45 to compel non-party Georgetown Economic Services, LLC ("GES"), to comply with a subpoena seeking documents relating to GES's data analyses of a study performed by Defendants in the above-captioned case filed in the United States District Court for the Southern District of New York.[1] GES has refused to produce any documents, claiming through broad, boilerplate objections that the subpoena seeks documents protected by the attorney-client privilege, the work

[1] GES is a subsidiary of Kelley Drye & Warren LLP, the law firm representing the corporate Defendants in the Southern District of New York litigation. GES, as a separate corporate entity, is a third party to the litigation. Kelley Drye is counsel for GES with regard to the subpoena.

product doctrine, and the protection afforded non-testifying experts.[2] GES's objections are meritless because Defendants have waived all privilege and protections by providing copies of GES's work to the FTC in the course of settlement discussions, by including the results of one analysis in a manuscript posted on Defendants' website, and by relying on that manuscript in their motion to dismiss Plaintiffs' complaint. Having used GES's work as a sword to better its position in this litigation, Defendants cannot now seek to shield it from the FTC on the grounds of privilege. The FTC is entitled to GES's analyses and, to prevent unfairness to the FTC, to all related documents in order to determine the accuracy of the results proffered by Defendants in this case.

I. FACTUAL BACKGROUND

A. Litigation

The FTC, together with its co-plaintiff the People of the State of New York by the Attorney General of the State of New York (NYAG) (collectively Plaintiffs), filed a Complaint on January 9, 2017 in the United States District Court for the Southern District of New York.[3] *See* Declaration of Michelle Rusk ("Rusk Decl.") at ¶ 2 and Complaint attached as Exhibit A thereto. The Complaint alleges that the above-captioned Defendants, Quincy Bioscience Holding Co., Inc. et al., have made false and unsubstantiated claims that Prevagen, a dietary supplement with the active ingredient apoaequorin, improves memory and provides other cognitive benefits. Complaint at ¶¶ 36-41; 44-45. The primary purported basis for these claims is a study, conducted by Quincy and known as the Madison Memory Study, in which subjects

[2] Although GES, rather than Defendants, asserted the objections, the FTC for purposes of this motion is treating the objections as if they had been made by Defendants.

[3] Although the NYAG is a co-plaintiff in the litigation against Quincy Bioscience Holding Co., Inc. and the other defendants, the FTC issued the subpoena to GES. The NYAG is not a party to this motion to compel.

who took either Prevagen or a placebo were tested on nine computerized cognitive tasks. The Complaint alleges that, when this study failed to show a statistically significant difference between the treatment and placebo groups on any of the nine cognitive tests, Defendants proceeded to conduct more than 30 post hoc analyses on different subgroups of the study population in an attempt to find at least some positive findings on some cognitive tests. *Id.* at ¶¶ 28-29. The Complaint alleges that this methodology greatly increases the probability that some statistically significant differences might occur by chance alone, given the sheer number of post hoc analyses. Even so, the vast majority of post hoc comparisons failed to show statistically significant differences between the treatment and placebo groups. *Id.* at ¶ 29. The Complaint asserts that the few positive findings on isolated tasks in the post hoc subgroup analyses do not provide reliable evidence of a treatment effect. *Id.* The Complaint states further that Defendants prominently featured the Madison Memory Study in their advertising for Prevagen. *Id.* at ¶ 30.

The FTC opened an investigation into the marketing of Prevagen in 2015 and obtained data regarding the Madison Memory Study from Defendants in response to a Civil Investigatory Demand served on Defendants that same year. Rusk Decl. at ¶ 3. In subsequent discussions prior to the filing of the joint Complaint with the NYAG, Plaintiffs raised multiple concerns about the Madison Memory Study, objecting to Defendants' selective reliance, after the fact, on only two subgroups with purported favorable results. *Id.* at ¶ 4. Plaintiffs pointed out that even those favorable post hoc subgroup analyses appeared to contain statistical errors. *Id.* In response, Defendants commissioned GES to conduct a new analysis of the Madison Memory Study data. *Id.* at ¶ 5. On April 22, 2016, Defendants provided Plaintiffs the GES re-analysis ("GES Re-Analysis") of the two post hoc subgroups. *Id.* The GES Re-Analysis also served as the basis for a revised August 1, 2016 manuscript of the Madison Memory Study (the "Lerner

Manuscript"), which was provided to Plaintiffs as an attachment to an October 17, 2016 letter. *See id.* at ¶ 6.

Defendants subsequently attached the Lerner Manuscript (containing the results of the GES Re-Analysis) to their April 6, 2017 Motion to Dismiss the Complaint and also posted it on the Prevagen website at https://www.prevagen.com/research/. *See id.* at ¶ 7 and Exhibit B thereto at 2. The Lerner Manuscript and the GES work described in that manuscript are thus a matter of public record in the case and publicly available on Defendants' website.

The Southern District of New York dismissed the complaint on September 28, 2017, but the Second Circuit reversed and remanded the case on February 21, 2019. *Id.* at ¶ 8. Following remand, Defendants presented to Plaintiffs yet another re-analysis performed by GES of the subgroup data from the Madison Memory Study. *Id.* at ¶ 9. For this re-analysis, GES applied a "Seemingly Unrelated Regressions" analysis, a methodology typically used in econometric research rather than human clinical research. Defendants presented the results of this econometric analysis ("GES SUR-Analysis") to bolster their defense that the Madison Memory Study results substantiated their marketing claims.

B. GES Subpoena

The FTC's subpoena, served on GES's registered agent on December 11, 2019, commanded GES to produce the following documents, among others:

1. All documents concerning the scope of work to be performed, services to be provided, or compensation to be provided for work performed by GES with regard to the Madison Memory Study.

2. All documents concerning any statistical analysis of any data derived from the Madison Memory Study, including but not limited to any pretest analysis, intent-to-treat

analysis, within-group or between-group analysis, subgroup analysis, supra-group analysis, re-analysis, post-hoc analysis, or seemingly unrelated regression (SUR) analysis.

3. All documents related to the design, protocol, and recruitment of subjects for the Madison Memory Study, including but not limited to any documents evidencing any inclusion or exclusion criteria for participation in the study.

4. All communications with any outside entity or person concerning the Madison Memory Study (including but not limited to any analyses of results or data of such study).

5. All documents relating to any other human clinical study commenced, discontinued, or completed by or on behalf of any Defendant involving apoaequorin or any product containing apoaequorin, including but not limited to any analysis of any data or results from any such study.

See Rusk Decl. at ¶ 10 and Exhibit C thereto at Attachment A, at 1-4.

GES replied to the subpoena on December 26, 2019, stating that it would not be producing documents in response to any of the specifications. GES stated that:

> GES objects to the Subpoena, including the definitions contained therein, to the extent it seeks the production of materials protected by disclosure by the attorney-client privilege and the attorney work product doctrine including, but not limited to, protection under Rule 26(b)(4)(D) of the Federal Rules of Civil Procedure. GES was retained as a consulting expert in connection with an attempt to resolve this dispute with the FTC and is not expected at this time to be called as a witness in any trial of this action; therefore all documents and information in the possession of GES are protected from disclosure.

See Rusk Decl. at ¶ 11 and Exhibit D thereto at 1.

Neither GES nor Defendants produced a privilege log or any other description of the nature of the withheld documents. *Id.* at ¶ 12. The parties discussed the subpoena and GES's response on January 16, 2020 and conferred regarding the instant motion on April 2, 2020. *Id*. at

¶ 13. The parties have been unable to resolve their differences regarding the GES documents, and Defendants have indicated that they will oppose this motion. *Id.* at ¶ 14.

II. LEGAL STANDARDS

A. Motion to Compel

Rule 45 allows parties to seek relevant documents, electronically stored information, and tangible things in the possession, custody, or control of third parties. Fed. R. Civ. P. 45(a)(1)(A)(ii). When withholding subpoenaed information on the basis of privilege or work product protection, the recipient must: (1) expressly make the claim; and (2) describe the nature of the material in a manner enabling the parties to assess the claim. *Id.* at 45(e)(2)(A). The rule also provides that, after providing notice to the subpoena recipient, the serving party may move to compel production. *Id.* at 45(d)(2)(B)(i). The person refusing production bears the burden to prove undue burden or that requested documents are privileged. *See In re Denture Cream Prods. Liab. Litig.*, 292 F.R.D. 120, 123 (D.D.C. 2013). Furthermore, "[t]he person objecting to production has a heavy burden to show that the subpoena should not be enforced." *Id.* (quotation and citation omitted)

B. Waiver of Privilege and Protection

Attorney client privilege and work product protection, including the protections afforded non-testifying experts, are waived when a party affirmatively uses protected materials in a manner inconsistent with the purposes of the privilege, *e.g.*, by disclosing protected materials to an adversary or filing such materials in litigation. *See In re Sealed Case*, 676 F.2d 793, 818 (D.C. Cir. (1982) ("Courts need not allow a claim of privilege when the party claiming the privilege seeks to use it in a way that is not consistent with the purpose of the privilege."). A party may waive attorney client privilege through selective disclosure and waive work product

protection by seeking "greater advantage from its control over work product than the law must provide to maintain a healthy adversary system." *Id.* *See also SEC v. Lavin*, 111 F.3d 921, 933 (D.C. Cir. 1997) ("The prohibition against selective disclosure of confidential materials derives from the appropriate concern that parties do not employ privileges both as a sword and shield.").

Parties thus waive privilege and protection when they disclose protected materials to adversaries in the course of settlement negotiations. *See In re Chrysler Motors Corp. Overnight Evaluation Program Litig.*, 860 F.2d 844, 846 (8th Cir. 1988) (plaintiff waived work product protection by voluntarily disclosing material to adversaries during settlement negotiations); *In re Martin Marietta Corp.*, 856 F.2d 619, 622 (4th Cir. 1988) (party waived privilege by disclosing privileged materials to government in course of settling charges in separate litigation); *Atari v. Sega of Am.*, 161 F.R.D. 417, 418-20 (N.D. Cal. 1984) (party waived all protection afforded to non-testifying experts by providing opposing party with material during settlement negotiations). *See also Chubb Integrated Sys. Ltd. v. Nat'l Bank of Washington*, 103 F.R.D. 52, 67 (D.D.C. 1984) ("Voluntary disclosure to an adversary waives both the attorney-client and work-product privileges.").

Parties also waive privilege and protection, including that for consulting experts, when they make affirmative use of protected material in litigation, *e.g.*, by filing such material in relation to a dispositive motion. *See Zeiger v. WellPet LLC*, Case No. 17-cv-04056-WHO, 2018 WL 10151156, at *2-3 (N.D. Cal. Apr. 10, 2018) (finding that consulting expert protection was waived where party referenced testing results in complaint and relied on results in overcoming motion to dismiss). As the court explained in *Zeiger*, "[b]y injecting the lab results into the litigation in connection with a dispositive motion, [the plaintiff has] affirmatively used these materials against [the defendant] and cannot now claim the expert consulting privilege to shield

these same materials from discovery." *Id.* at *3. *See also In re Morning Song Bird Food Litig.*, Case No. 12cv1592 JAH(RBB), 2015 WL 12791470, at *7 (S.D. Cal. Jan. 23, 2015) (consulting expert protection for reports waived where defendants voluntarily disclosed the contents of the reports to authorities and attached a letter discussing and summarizing one report to their motion to dismiss); *Worley v. Avanquest North America Inc.*, No. C 12-04391 WHO (LB), 2013 WL 6576732, at *4 (N.D. Cal. Dec. 13, 2013) (consulting expert privilege waived where plaintiff referenced results of experts' investigation in complaint and relied on results in opposing motion to dismiss; "if a party uses a consulting expert's statements, findings, or opinions in a filing, that party has put the expert's statements, findings, or opinions into the judicial arena and the opposing side may take discovery about those statements, findings, or opinions").

In addition, parties waive protection when making materials available to the public. *See In re Intel Corp. Microprocessor Litig.*, No. 05-441-JJF, 2008 WL 11233766, at *8-14 (D. Del. March 6, 2008) (party waived protection for non-testifying expert's report and underlying documents by disclosing report, expert's name, and report's key findings and methodology in press release).

C. Scope of Waiver

Parties disclosing or relying on protected materials in the course of litigation may waive protection not only for the actual materials disclosed, but also for all communications and information related to the same subject matter. Federal Rule of Evidence 502 provides that when a disclosure of protected material has waived the attorney-client privilege or work-product doctrine, the waiver extends to undisclosed communications or information only if (1) the waiver is intentional; (2) the disclosed and undisclosed communications or information concern the same subject matter; and (3) they ought in fairness to be considered together. Fed. R. Evid.

502(a). Courts applying Rule 502 have found that such "subject matter waiver" is appropriate "as a matter of fairness where 'the privilege holder seeks to use the disclosed material for advantage in the litigation but to invoke the privilege to deny its adversary access to additional materials that could provide an important context for proper understanding of the privileged materials.'" *US Airline Pilots Ass'n v. Pension Benefit Guar. Corp.*, 274 F.R.D. 28, 32 (D.D.C. 2011) (quoting Charles A. Wright, 8 Fed. Prac. & Proc. § 2016.2 (3d ed., 2010 update)). *See also Navajo Nation v. Peabody Holding Co.*, 255 F.R.D. 37, 47 (D.D.C. 2009) ("The doctrine of subject matter waiver dictates that once a party waives privilege over a document, an adverse party may discover all documents and communications arising out of the same transaction. . . . Subject matter waiver prevents a party from selectively disclosing materials to confuse and mislead an adverse party."); *Bowles v. Nat'l Ass'n of Home Builders*, 224 F.R.D. 246, 258-59 (D.D.C. 2004) (subject matter appropriate in case of disclosure and use of documents in a manner inconsistent with the purpose of the work product doctrine – the partial release of documents to gain a tactical advantage);[4] *City of Capitola v. Lexington Ins. Co.*, No. 12-3248 LHK (PSG), 2013 WL 1087491, at *1-2 (N.D. Cal. March 13, 2013) ("Courts are in accord that the attorney work-product privilege is not absolute and may be waived, for example, when an attorney attempts to use the work-product as testimony or evidence, or reveals it to an adversary to gain an advantage in litigation. Waiver for the benefit of the party who owns the privilege precludes limiting the waiver to avoid disclosing disadvantageous information.") (quotation and citation omitted) (finding that fairness mandated subject matter waiver entitling defendant to

[4] Although *Bowles* pre-dates Rule 502, implementation of the rule in 2008 did "not alter the substantive law regarding when a party's strategic use in litigation of otherwise privileged information obliges that party to waive the privilege regarding other information concerning the same subject matter, so that the information being used can be fairly considered in context." Fed. R. Evid. 502 Addendum to Advisory Comm. Notes.

entire investigatory file of plaintiff's expert consultant where plaintiff had disclosed to defendant only certain documents pertaining to consultant's analysis and conclusions in order to support its position).

III. ARGUMENT

Defendants have waived all privilege and work product protection for both the GES Re-Analysis and the GES SUR-Analysis of subgroup data from the Madison Memory Study by disclosing those analyses during settlement negotiations and, in the case of the GES Re-Analysis, by attaching the results to a dispositive motion and publishing them on their website.[5] Furthermore, having used the GES analyses to gain an advantage in the case, Defendants have waived these protections for all documents related to the subject matter of the analyses and any related analyses of data from the Madison Memory Study or related research on Prevagen. Fundamental fairness mandates that Plaintiffs are entitled to these related documents to determine the scope and nature of GES's work regarding the Madison Memory Study data and ensure that Defendants have not selectively produced only GES's favorable analyses while withholding other contradictory analyses that might call into question Prevagen's efficacy.

A. Waiver Through Disclosure in Settlement Discussions and Use in Litigation

As set forth above, Defendants provided the GES Re-Analysis and underlying data, as well as the GES SUR-Analysis, to Plaintiffs during settlement discussions. They disclosed the GES Re-Analysis, and referred to its findings in multiple letters, in an effort to convince

[5] Defendants in fact have failed to sustain their burden with regard to all of their objections, including those relating to undue burden, as they have not adduced any evidence in support thereof. *See In re Denture Cream Prods.*, 292 F.R.D. at 123 (burden is on party resisting discovery to establish undue burden and privilege); *Alexander v. FBI*, 194 F.R.D. 316, 326 (D.D.C. 2000) (party objecting on the basis of undue burden "must make a specific, detailed showing of how the discovery request is burdensome"). Plaintiffs nonetheless address the merits of Defendants' objections on the basis of privilege and work product protection, as those objections appear to be the basis for GES's refusal to produce any documents.

Plaintiffs that the Madison Memory Study was a credible study demonstrating Prevagen's efficacy and that Plaintiffs thus should close their investigation. Additionally, following the Second Circuit's remand, Defendants provided Plaintiffs with the GES SUR-Analysis in an effort to convince Plaintiffs not to continue with the litigation. Providing these GES analyses to Plaintiffs during settlement talks is contrary to the purpose of privilege and protection and waives any such protections for these materials. *See In re Chrysler Motors Corp.*, 860 F.2d at 846 (plaintiff waived work product protection by voluntarily disclosing material to adversaries during settlement negotiations); *Atari*, 161 F.R.D. at 420 (finding that party waived all protection afforded to non-testifying experts by providing opposing party with material during settlement negotiations).

Defendants also waived all protection for the GES Re-Analysis results by including those results in a manuscript submitted with their motion to dismiss. Having used the GES Re-Analysis as a sword in such a manner, they cannot now seek to use privilege as a shield to prevent Plaintiffs from obtaining the requested documents. *See Zeiger*, 2018 WL 10151156, at *3 ("By injecting the lab results into the litigation in connection with a dispositive motion, [the plaintiff has] affirmatively used these materials against [the defendant] and cannot now claim the expert consulting privilege to shield these same materials from discovery."). The same principle mandates that Defendants waived protection for the GES Re-Analysis results by posting them on their website in an effort to bolster their claims regarding the efficacy of their product. *See In re Intel Corp.*, 2008 WL 11233766, at *9 (party claiming protection for report of non-testifying expert and underlying documents may not "hypocritically claim that they are confidential one moment and then so share such information with a host of others to be used for something other than litigation") (quote and internal edits omitted).

B. Subject-Matter Waiver is Appropriate

Furthermore, fundamental fairness mandates that by seeking to use the GES analyses in this manner to further their position in this case, Defendants have waived protection for all documents relating to these and any other related analyses of the data. Such a result is necessary to prevent Defendants from selectively producing only positive findings of GES while shielding from discovery other results that "ought in fairness" to be considered as well to allow for a more accurate assessment of the Madison Memory Study results. The FTC cannot adequately assess GES's two post hoc re-analyses of the Madison Memory Study without underlying information about related work done by GES on this data or data from related studies of Prevagen. GES's reasoning for selecting a specific subgroup to analyze, whether GES ran analyses of other subgroups of the study population with different results, the justification for applying a non-traditional methodology to its second analysis, and whether GES did so only after traditional methodologies failed to yield the desired outcomes are all relevant to determining how to weigh the work GES chose to share with the FTC and the Court.

The court's holding in *US Airline Pilots Association* is instructive. In that case, the plaintiff alleged that the defendant had breached its duty as the trustee of a pension plan of which the plaintiff's members were beneficiaries. *US Airline Pilots Ass'n*, 274 F.R.D. at 29. The plaintiff moved to compel the deposition of defendant's in-house attorney who had conducted an investigation into the alleged misconduct and produced a report documenting her findings, which the defendant subsequently provided to the plaintiff. *Id.* When the plaintiff sought to depose the attorney regarding the substance and scope of her investigation, the defendant claimed that the investigation was protected by the work-product doctrine. *Id.* at 29-30. The plaintiff argued that the defendant's disclosure of the report waived work-product protection not only for the report

itself, but also for the investigation as a whole. *Id.* at 30. The plaintiff contended that subject matter waiver was appropriate because the defendant had made a tactical decision to disclose only favorable protected material. *Id.* The defendant, in the plaintiff's view, was attempting to use work product doctrine "as both a sword and shield" by relying on the report to show that it had not violated the law, yet preventing the plaintiff from questioning the attorney regarding the sufficiency of her efforts. *Id.* at 31.

The court found that the defendant's disclosure and use of the report resulted in a subject matter waiver of protection for the attorney's investigation and findings. *Id.* at 32-33. Analyzing the case under Federal Rule of Evidence 502, the court found that the defendant had intentionally waived work product protection for the attorney's report by deliberately disclosing it to the plaintiff. *Id.* at 31. The court then examined whether "the disclosed and undisclosed materials 'ought in fairness to be considered together.'" *Id.* (quoting Fed. R. Evid. 502(a)(3)). The court noted that the defendant had relied on the investigation throughout the course of the litigation, and had attached a copy of the attorney's report to its opposition to plaintiff's motion for a preliminary injunction. *Id.* at 32. The court ruled that, having made use of the report to benefit its position, the defendant could

> not now use the work-product privilege to deny its adversary access to additional materials that could provide an important context for proper understanding of the [r]eport. . . . When a party puts privileged material in issue as evidence in a case, it thereby waives the privilege as to all related privileged matters on the same subject.

Id. (internal quotes and citations omitted).

Accordingly, the court ruled that the plaintiff was entitled to question the attorney "regarding 'undisclosed communications or information concern[ing] the same subject matter' as the [r]eport." *Id.* at 32-33. Specifically, the court found that the "same subject matter" of the report

included: "the scope and methods of the investigation; the documents reviewed; the efforts made to obtain more documents; the [pension plan's] investment policy; the [trust's] policies and procedures; and [the attorney's] findings." *Id.* at 33. The plaintiff thus was entitled to ask the attorney about the "scope, conduct, participants, and conclusions of the investigations" in which she had participated. *Id.*

Defendants in the instant case have sought to use GES's work in the same manner as the defendants in *US Airline Pilots Ass'n*. They deliberately disclosed two analyses conducted by GES and referred to them repeatedly in an effort to prove that their advertising claims were substantiated and that Plaintiffs should close their case. In addition, Defendants affirmatively injected the results of the GES Re-Analysis into their advertising via their website and even into the litigation when they used those results to support their motion to dismiss. Having used GES's work to support their case in this way, Defendants cannot now "invoke the privilege to deny [their] adversary access to additional materials that could provide an important context for proper understanding of the privileged materials." *US Airline Pilots Ass'n*, 274 F.R.D. at 32 (quote omitted).

Without a complete picture of just how extensively GES mined the data from the Madison Memory Study in order to find some outcome that appeared to be favorable to Defendants' case, the FTC cannot adequately assess the validity of the results selectively shared by Defendants. The more analyses performed by GES on the Madison Memory data, the greater the number of subgroups analyzed, and the more methods applied to interpret that data, the more likely it is that one or more results would appear to be statistically significant merely as a matter of chance. In the case of the GES SUR-Analysis, Plaintiffs are entitled to know what considerations went into GES applying an econometric methodology rarely used for clinical

research, and whether GES applied more traditional methodologies that were not turned over because they yielded unfavorable results. Finally, Plaintiffs should be given access to all work done by GES for Defendants, not just on the Madison Memory Study, but also on any other relevant studies of the product. The Madison Memory Study cannot be fairly assessed in isolation, but must be considered in the context of all relevant scientific literature on Prevagen, both favorable and not. Any work GES may have done to analyze the results of other clinical studies on Prevagen would have direct bearing on the weight of GES's work on the Madison Memory Study.

The FTC is entitled to a full picture of GES's work to assess the specific analyses that Defendants selectively shared. All analyses, not just favorable ones, "ought in fairness" to be considered together to determine how much weight should be given to the Madison Memory Study – the single piece of evidence most central to this case. *See* Fed. R. Evid. 502(a)(3). The Court should reach the same result as in *US Airline Pilots Ass'n* and compel GES to turn over all communications and documents related to the GES work commissioned by Defendants as requested in the FTC's subpoena.

IV. CONCLUSION

For the above reasons, the FTC respectfully requests that the Court grant its motion and compel GES to produce the requested documents.

Dated: April 10, 2020

FEDERAL TRADE COMMISSION
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UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION and THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York, Plaintiffs, v. QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation; QUINCY BIOSCIENCE, LLC, a limited liability company; PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS; QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC. Defendants.	Misc. No.: [S.D.N.Y Case No. 1:17-cv-00124-LLS] **DECLARATION OF MICHELLE RUSK IN SUPPORT OF MOTION TO COMPEL PRODUCTION OF DOCUMENTS PURSUANT TO FED. R. CIV. P. 45**

I, Michelle Rusk, certify and declare as follows:

1. I am an attorney employed by and representing the Federal Trade Commission ("FTC") in this case. My business address is 600 Pennsylvania Ave., N.W., CC-10528, Washington, D.C., 20580. The facts set forth herein are based on my personal knowledge or information made known to me in the course of my official duties, and if called as a witness I could competently testify thereto.

2. I have attached hereto as Exhibit A a true and correct copy of the Complaint for Permanent Injunction and Other Equitable Relief ("Complaint") filed by the FTC and the New York Attorney General's Office on January 9, 2017 in the United States District Court for the Southern District of New York against Defendants, Quincy Bioscience Holding Company, Inc. *et al*.

3. In 2011, Defendant Quincy Bioscience Holding Company, Inc. ("Defendant") completed a clinical trial known as the Madison Memory Study regarding its dietary supplement, Prevagen, and published a paper describing purported findings from the study in late 2015 or early 2016. In 2015, the FTC opened an investigation into the marketing of Prevagen and, through compulsory process, obtained data regarding the Madison Memory Study from Defendant.

4. After reviewing this information but before filing the Complaint, Plaintiffs raised concerns about the Madison Memory Study, objecting to Defendants' selective reliance, after the fact, on only two subgroups with purported favorable results. Plaintiffs pointed out that even these subgroup analyses appeared to contain statistical errors.

5. In response, and at Defendant's request, subpoena recipient Georgetown Economic Services, LLC, re-analyzed the data from the two subgroups. Counsel for Defendants shared the results of this re-analysis (the "GES Re-Analysis") with Plaintiffs by letter dated April 22, 2016.[1]

6. An employee for Quincy, Kenneth Lerner, subsequently authored a revised write-up of the Madison Memory Study to incorporate the GES Re-Analysis and published this revised

[1] The FTC is not attaching Defendants April 22, 2016 letter due to the sensitivity of some of its contents. The FTC would be happy to provide the document to the Court for *in camera* review at the Court's request.

version (the "Lerner Manuscript") on August 1, 2016, titled "Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling Older Adults." On October 17, 2016, defense counsel attached the Lerner Manuscript to a letter addressed to the FTC's Director of the Bureau of Consumer Protection, Jessica Rich. The letter acknowledged that the GES Re-Analysis that Defendants' counsel shared with Plaintiffs on April 22, 2016 formed the basis for the Lerner Manuscript. Specifically, footnote 24 of the letter states:

> *See* Lerner, Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling Older Adults (Aug. 1, 2016), *enclosed as* QB-002199 through QB-002208 (provided to Staff via email June 20, 2016). *This manuscript was based on a reanalysis of the data conducted on behalf of Quincy by Georgetown Economic Services*. We discussed the quantitative results of the reanalysis in a prior submission to Staff. See Letter from John E. Villafranco, Kelley Drye & Warren LLP, to Michelle Rusk, FTC, at 5 (April 22, 2016) (discussing the reanalysis and providing the underlying dataset at Exhibit D).[2]

(Emphasis added.)

7. Defendants subsequently filed the Lerner Manuscript with the Southern District of New York in support of their Motion to Dismiss. Attached hereto as Exhibit B is a true and correct copy of the Declaration of Glenn Graham, with Exhibit 1 thereto, filed by Defendants on April 6, 2017 in conjunction with Defendants' Motion to Dismiss. The Declaration states that Exhibit 1 is a true and correct copy of the manuscript authored by Kenneth Lerner, titled, "Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling Older Adults." Mr. Graham's declaration also states that

[2] The FTC is not attaching the October 17, 2016 letter due to the sensitivity of some of its contents. The FTC would be happy to provide the letter to the Court for *in camera* review at the Court's request.

this document was publicly available on Defendants' website, https://www.prevagen.com/research/. It is identical to the Lerner Manuscript produced to Plaintiffs as described in Paragraph 6 above and is based on the GES Re-Analysis described in Paragraph 5.

8. The Southern District of New York dismissed the case on September 28, 2017, but the Second Circuit vacated that dismissal and remanded the case on February 21, 2019.

9. Following remand and at Defendants' request, GES conducted a *different* re-analysis of the Madison Memory Study that purported to apply a Seemingly Unrelated Regressions (SUR) methodology to analyze the study data ("the GES SUR-Analysis"). Defendants provided the GES SUR-Analysis, entitled "Madison Memory Trial: An Expanded Analysis," to Plaintiffs on July 18, 2019. J. Howard Beales III of the George Washington School of Business, as well as Janet Liang Ph.D. and Robert N. Fenili Ph.D. of GES, authored the GES SUR-Analysis.[3]

10. I have attached hereto as Exhibit C a true and correct copy of the FTC's subpoena served on the registered agent of Georgetown Economic Services, LLC on December 11, 2019.

11. I have attached hereto as Exhibit D a true and correct copy of Non-Party Georgetown Economic Services, LLC's Objections and Responses to Federal Trade Commission's Subpoena to Produce Documents, Information, or Objects, served on the FTC on December 26, 2019.

12. Neither Georgetown Economic Services, LLC nor Defendants produced a privilege log or any other description of the nature of the withheld documents.

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[3] The FTC is not attaching the July submission or the exhibits thereto due to the sensitivity of some of its contents. The FTC would be happy to provide the documents to the Court for *in camera* review at the Court's request.

13. The parties discussed the subpoena and GES's response on January 16, 2020. The parties conferred regarding the instant motion to compel on April 2, 2020.

14. The parties have been unable to resolve their differences regarding the GES documents. Defendants have indicated that they will oppose this motion.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in Arlington, VA on April 10, 2020.

/s/ Michelle Rusk
MICHELLE RUSK
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Federal Trade Commission
600 Pennsylvania Ave., NW; Room CC-10528
Washington, DC 20580
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Attorney for Plaintiff
FEDERAL TRADE COMMISSION

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company;

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.; and

MICHAEL BEAMAN, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.

Defendants.

Case No.

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiffs, the Federal Trade Commission ("FTC") and the People of the State of New York, by their attorney Eric T. Schneiderman, Attorney General of the State of New York ("NYAG"), for their Complaint allege:

1. The FTC brings this action under Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to obtain permanent injunctive relief, rescission or

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reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for the acts or practices of Defendants' Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark Underwood, and Michael Beaman (collectively, "Defendants") in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, promotion, distribution, and sale of Prevagen, a dietary supplement that purportedly improves memory. Prevagen contains one active ingredient, the dietary protein apoaequorin, and it is sold in a variety of strengths and forms.

2. The People of the State of New York bring this action under New York Executive Law ("NY Exec. Law") § 63(12), which authorizes their attorney, the NYAG, to bring an action for injunctive relief, restitution, damages and costs against any person or business that has engaged in repeated or persistent fraud or illegality in the conduct of his or its business, and New York General Business Law ("NY GBL") §§ 349 and 350, which authorize the NYAG to bring an action for injunctive relief, restitution and penalties whenever any person, firm, corporation or association or agent or employee thereof has engaged in deceptive business practices and false advertising. This action is brought against Defendants in connection with the labeling, advertising, marketing, promotion, distribution, and sale of Prevagen.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b).

4. This Court has supplemental jurisdiction over the NYAG's claims under 28 U.S.C. § 1367.

5. Venue is proper in this district under 28 U.S.C. §§ 1391(b)(2), (b)(3), (c)(2), and (d), and 15 U.S.C. § 53(b).

PLAINTIFFS

6. Plaintiff FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

7. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. § 53(b).

8. The NYAG is authorized to take action to enjoin repeated and persistent fraudulent and illegal business conduct under NY Exec. Law § 63(12) and deceptive business practices and false advertising under NY GBL §§ 349 and 350 and to obtain equitable or other appropriate relief, including restitution, damages, disgorgement of ill-gotten monies and penalties as may be appropriate.

DEFENDANTS

9. Defendant Quincy Bioscience Holding Company, Inc. is a Wisconsin corporation with its principal place of business at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience Holding Company, Inc. transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Quincy Bioscience Holding Company, Inc., through its wholly-owned

subsidiaries, has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including New York.

10. Defendant Quincy Bioscience, LLC is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin limited liability company with its principal place of business at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience, LLC transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Quincy Bioscience, LLC has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including New York.

11. Defendant Prevagen, Inc., also doing business as Sugar River Supplements, is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin corporation with its principal place of business at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Prevagen, Inc. transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Prevagen, Inc. has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including New York.

12. Defendant Quincy Bioscience Manufacturing, LLC is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin corporation with its principal place of business at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience Manufacturing, LLC transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Quincy Bioscience Manufacturing, LLC has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including New York.

13. Defendant Mark Underwood ("Underwood") is the co-founder and President of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc. Underwood is a member of the Board of Directors of Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC and a shareholder of Quincy Bioscience Holding Company, Inc., owning 33 percent of shares, the largest individual ownership interest. Underwood, in connection with the matters alleged herein, transacts or has transacted business in this district and throughout the United States, including New York.

14. At all times material to this Complaint, acting alone or in concert with others, Underwood has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc., including the acts and practices set forth in this Complaint. Underwood is a member of the marketing creative team, serving as the final decision maker on advertising claims across all channels of distribution and media platforms. Underwood coordinates advertising claim language review with counsel, translates scientific data into marketing language, and directs research programs and activities. Underwood has appeared in infomercials aired nationwide, including in New York, touting Prevagen's memory improvement benefits and has co-authored studies on Prevagen. Underwood also authored the "Brain Health Guide," a user guide disseminated nationwide, including in New York, that describes how Prevagen works and the purported science behind this dietary supplement.

15. Defendant Michael Beaman ("Beaman") is the co-founder, former President, and current Chief Executive Officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc. Beaman is the Chair of the Board of Directors for Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC and a shareholder

of Quincy Bioscience Holding Company, Inc., owning 22 percent of shares, the second largest individual ownership interest. Beaman, in connection with the matters alleged herein, transacts or has transacted business in this district and throughout the United States, including New York.

16. At all times material to this Complaint, acting alone or in concert with others, Beaman has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc., including the acts and practices set forth in this Complaint. Beaman has given media interviews, signed research agreements, pre-approved research proposals, and reviewed Defendants' advertising, including advertising that has been disseminated nationwide, including in New York.

17. Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC (collectively, "Corporate Defendants") have operated as a common enterprise while engaging in the deceptive acts and practices alleged below. These Corporate Defendants have conducted the business practices described below through an interrelated network of companies that have common ownership, officers, managers, business functions, employees, and office locations. Because these Corporate Defendants have operated as a common enterprise, each of them is jointly and severally liable for the acts and practices alleged below. Defendants Beaman and Underwood have formulated, directed, controlled, had the authority to control, or participated in the acts and practices of the Corporate Defendants that constitute the common enterprise.

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COMMERCE

18. At all times material to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS' BUSINESS ACTIVITIES

19. Prevagen is a dietary supplement containing the active ingredient apoaequorin, a dietary protein, which according to Defendants was originally obtained from a species of jellyfish called *Aequorea victoria*. Prevagen is available in Regular Strength (10 milligrams) and Extra Strength (20 milligrams) capsules and chewable versions, and Prevagen Professional (40 milligrams) capsules (collectively, "Prevagen Products").

20. A bottle of each Prevagen Product contains 30 tablets and provides a 30-day supply if taken once daily according to the product label's suggested use. The price per bottle varies depending on the seller, with prices ranging from $24.29 to $58.53 for Prevagen Regular Strength, $32.17 to $69.95 for Prevagen Extra Strength, $16.49 to $51.29 for Prevagen Chewable, and $39.33 to $68.40 for Prevagen Professional.

21. Since at least 2007, Defendants have labeled, advertised, marketed, promoted, distributed, and sold the Prevagen Products to the public and healthcare practitioners through their own websites, Prevagen.com, QuincyBioscience.com, PrevagenPro.com, PrevagenES.com, SugarRiverSupplements.com, and through health stores, pharmacies, retail stores, and retail websites, including Amazon, CVS, Duane Reade, Rite-Aid, Meijer, the Vitamin Shoppe, and Walgreens. Sales of Prevagen in the United States from 2007 through mid-2015, minus refunds, totaled $165 million.

22. Defendants have widely advertised the Prevagen Products through their own websites, Prevagen.com, QuincyBioscience.com, PrevagenPro.com, PrevagenES.com, PrevagenReviews.com, SugarRiverSupplements.com, and HopeTrials.com, as well as through infomercials, short form television commercials, radio, social media, newspapers, and magazines.

23. Defendants' infomercials aired frequently as the "Better Memory Show" from July 2013 to April 2015. They employed an interview format and featured Defendant Mark Underwood, explaining the problems associated with memory loss, the purported benefits of the Prevagen Products, and research purportedly supporting Defendants' memory-improvement claims.

24. Defendants' short-form television advertisements have aired nationally on broadcast and cable networks, including CNN, Fox News, and NBC, and their radio campaign includes spots on internet and satellite radio services such as Sirius and iHeartRadio.

25. Defendants have an active social media presence with accounts on Facebook, Instagram, Twitter, Pinterest, and YouTube.

26. Defendants' advertising campaign also included a 2015 "Better Memory Tour." Company representatives traveled aboard the "Prevagen Express" bus to various health food centers and health expos across the country, showcasing the Prevagen Products and Defendant Mark Underwood's Brain Health Guide, which accompanies product orders and can be downloaded from Defendants' websites.

27. Defendants have represented, among other things, through express and implied claims and consumer and expert endorsements, that the Prevagen Products improve memory and provide other cognitive benefits, and that the Prevagen Products' effects on memory and

cognition are clinically proven. To induce consumers to purchase the Prevagen Products, Defendants have disseminated, or caused to be disseminated, advertisements, labeling, and other marketing materials, including, but not limited to, the attached Exhibits A through F. These advertisements contain the following statements and depictions, among others:

A. Prevagen Regular Strength Label (Exhibit A)

Supplement Facts

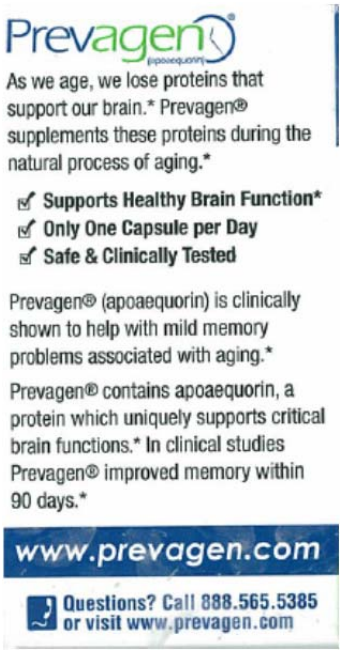
Serving Size: 1 capsule
Servings per container: 30

Amount per capsule		% Daily Value
Apoaequorin	10 mg	†

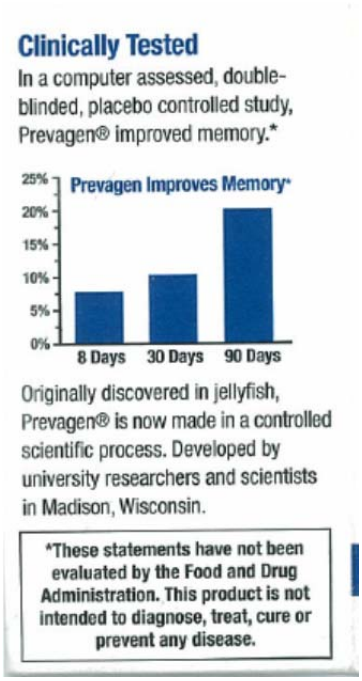
† Daily Value not established.

Other ingredients: white rice flour, cellulose, salt, magnesium stearate, acetic acid.
Manufactured & Distributed by Quincy Bioscience
301 S Westfield Road • Madison, WI 53717
Made without COMMON ALLERGENS
Suggested use: Take 1 vegetarian capsule daily in the morning, with or without food.

SIDE LABEL:



BACK LABEL:



B. Prevagen TV Ad – "Jellyfish Protein" (Exhibits B-1 (transcript) and B-2 (video))

ON SCREEN: Memory Improvement?

ANNOUNCER: Can a protein originally found in the jellyfish improve your memory?

ON SCREEN: QUINCY BIOSCIENCE

Our Scientists Say "Yes!"

ANNOUNCER: Our scientists say yes.

ON SCREEN: Actor portrayal [Screen depicts a smiling doctor wearing a white coat, with the words "Quincy Bioscience" and "Our Scientists Say "Yes!" appearing next to the doctor. In the next scene, another doctor in a white coat is looking into a microscope. The "Actor Portrayal" disclosure appears in both scenes in small print at the bottom of the screen.]

Supports Healthy Brain Function* [Appears in large font in the center of the screen]

*These statements have not been evaluated by the Food and Drug Administration.

This product is not intended to diagnose, treat, cure or prevent any disease. [This disclosure appears briefly in a box in much smaller font at the bottom of the screen.]

ANNOUNCER: Researchers have discovered a protein that actually supports healthier brain function. It's the breakthrough in a supplement called Prevagen.

ON SCREEN: Prevagen

Supplements Brain Proteins

ANNOUNCER: As we age, we lose proteins that support our brain.

ON SCREEN: Prevagen Improves Memory

Chart [A full-screen bar chart depicts memory improving significantly over 90 days]

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. [This disclosure appears briefly in a box in much smaller font at the bottom of the screen.]

ANNOUNCER: Prevagen supplements these proteins and has been clinically shown to improve memory.

ON SCREEN: Safe Effective

ANNOUNCER: It's safe and effective.

ON SCREEN: Available at Walgreens

CVS/pharmacy RITE AID

ANNOUNCER: For support of healthier brain function, a sharper mind and clearer thinking, try Prevagen for yourself today.

C. Website Capture, Prevagen.com, December 10, 2015 (Exhibit C)

Improve your memory with Prevagen ®*

Prevagen can improve memory*

Prevagen was tested in a large double-blind, placebo-controlled study using computers to assess brain performance. 218 adults over 40 years old participated in the three month study. Prevagen significantly improved learning and word recall.*

Around the age of 40, our brain begins to need more cognitive support.* Prevagen can improve memory within 90 days.*

Common examples where Prevagen may help

- **Walk into a room and forget why.**
- **Spend extra time looking for car keys or purse.**
- **Trouble remembering names or faces.**

These are everyday examples of normal memory challenges that can come with aging. Prevagen has been tested and shown to improve memory.*

Prevagen is a safe and effective supplement

Only Prevagen contains the patented ingredient apoaequorin, a unique protein originally obtained from a specific species of jellyfish called Aequorea Victoria found in the Puget Sound. Apoaequorin is a protein our brains need for healthy function but is diminished in the aging process.

Prevagen is very safe and extremely well-tolerated. There are no known contraindications with any supplements or medications

Make Memories Last a Lifetime

There's nothing more fulfilling than being at your mental best in order to enjoy every moment with friends and family. But that can be difficult for some of us due to normal, age-related memory loss.

Order Now

How does Prevagen ® work?

Laboratory research has demonstrated that Prevagen has powerful cell supporting activity by providing a protein originally found in jellyfish.

In aging, these proteins are depleted leaving brain cells vulnerable to damage. Prevagen is made by Quincy Bioscience and was developed by scientists and University researchers in Madison, Wisconsin.

•••

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. [This disclosure refers back to each asterisk on this webpage. It appears in a box in white text against a blue background at the very bottom of the webpage.]

•••

Protein Chemistry

Apoaequorin is capable of crossing the blood brain barrier (BBB) and the GI barrier

When cerebrospinal fluid (CSF) and blood plasma samples were taken from a population of dogs to which apoaequorin was orally administered, these samples showed quantifiable evidence that the supplement was present in the nervous and circulatory systems of the animals. Using a specially designed enzyme-linked immunosorbent assay (ELISA) linked to an electrochemiluminescent assay, it was also demonstrated that apoaequorin levels in dog CSF and plasma increased proportionately as a function of time. These data indicate that apoaequorin is capable of crossing the blood brain barrier and the gastrointestinal barrier via its presence in dog CSF and blood plasma, respectively.

As we age, we lose about 85,000 brain cells each day.

Aging and how Prevagen® can help

In the United States, 10,000 baby boomers turn 50 every day. And although a touch of gray hair can look distinguished, there are other age-related issues that may be unwanted, such as the mild memory problems associated with aging. Your brain is made up of many small cells, and controls everything you do. To stay healthy your brain contains proteins that support brain health.

As we age, the body's ability to naturally produce this protein slows down. When this happens you may start to experience difficulty with memory, focus and concentration. Prevagen helps support brain cells by supplementing the proteins with the patented ingredient apoaequorin and supports healthier brain function.*

Researchers have discovered a protein that actually supports healthy brain function*

For many years, researchers have known that the human brain loses cells throughout our lives, part of the natural process of aging. In fact, we lose about 85,000 brain cells per day, that is one per second, over 31 million brain cells every year! This impacts every aspect of your life… how you think and how you feel. Recently, scientists made a significant breakthrough in brain health with the discovery that apoaequorin can support healthy brain function, help you have a sharper mind and think clearer.*

Prevagen Supports:

Healthy Brain Function*
Apoaequorin is in the same family of proteins as those found in humans, but it was originally discovered in one of nature's simplest organisms—the jellyfish.

Sharper Mind*
Now produced in a scientific process, researchers formulated this vital protein into a product called Prevagen®. Prevagen is clinically shown to help with mild memory problems associated with aging.

Better Memory*
This type of protein is vital and found naturally in the human brain and nervous system. As we age we can't make enough of them to keep up with the brain's demands. Prevagen supplements these proteins during the natural process of aging to keep your brain healthy. Prevagen comes in an easy to swallow capsule. It has no significant side effects and will not interact with your current medication.

Clearer Thinking*
Just how well does Prevagen work? In a computer assessed, double-blinded, placebo controlled study, Prevagen improved memory for most subjects within 90 days.*

•••

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•••

Quincy Bioscience is a research-based biotechnology company

...

Prevagen® is the company's flagship consumer brand containing apoaequorin which has shown in published studies to be safe and effective. A landmark double-blind and placebo controlled trial demonstrated Prevagen improved short-term memory, learning, and delayed recall over 90 days.

As a result of the supplement's safety and effectiveness, Prevagen is now the number one selling brain support supplement in chain pharmacies across America according to Nielsen data (December 2014).

...

Nobel prize in chemistry

Apoaequorin (Pronounced: ā-poe-ē-kwôr-ĭn) was first discovered in 1962 in glowing jellyfish. Turns out these proteins caused the jellyfish to glow when the proteins bound to calcium ions. We've learned a lot about how calcium functions in the body by using apoaequorin. The Princeton professor who discovered this protein and his colleagues who helped develop the research won the Nobel prize in 2008. Prevagen does not cause any glowing!

Quincy Bioscience and Apoaequorin

Founded in June of 2004 and based in Madison, Wisconsin, Quincy Bioscience is a biotechnology company focused on the discovery, development, and commercialization of novel technologies to address cognitive issues and other age-related health challenges. The core technology of the company is the innovative application of the calcium-binding protein Apoaequorin. Using this cutting edge protein originally discovered in jellyfish in the early 1960s, the company focuses on alleviating the consequences of impaired calcium homeostasis (the imbalance of calcium ions) which can lead to mild memory loss associated with aging.

...

Frequently Asked Questions about Prevagen

...

What is Prevagen?
Prevagen (Pronounced: prev-uh-gen) is a new brain health supplement and functions unlike other brain or memory supplements.* Prevagen's patented ingredient is a new use for a well-known protein called "apoaequorin" which was originally found in a certain species of jelly fish.

Prevagen has been clinically tested and shown to improve mild memory problems that occur in aging.*

What are the most commonly reported benefits of Prevagen?

- Improves absentmindedness*
- Improves memory*
- Helps with mild memory problems associated with aging*

How long will it take to feel results?

Daily use for 30-90 days is a reasonable length of time to experience results.

Do you have research supporting Prevagen?

Yes. A recent memory study showed Prevagen significantly supported cognitive function compared to placebo.

View the study [links to the Madison Memory Study]

•••

What are all the asterisks (*) for?

The asterisk (*) denotes the FDA disclaimer for dietary supplements. This statement or "disclaimer" is required by law (DSHEA) when a manufacturer makes a structure/function claim on a dietary supplement label. In general, these claims describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by FDA. For this reason, the law says that if a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated this claim. The disclaimer must also state that this product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim. For more information on dietary supplements, please visit www.fda.gov

•••

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•••

Watch Prevagen Reviews

After over 15 years of research, we know Prevagen works to improve memory. But you don't have to take our word for it. On the following pages, you'll find Prevagen reviews from actual Prevagen users and hear how this brain health supplement, originally derived from a jellyfish, has helped them.

If you feel like you can relate to any of these people—whether you have trouble remembering names, or forget where you placed your keys—you may be experiencing age-related memory loss. This is a totally normal part of aging, but as you will see from watching these Prevagen reviews, you CAN take action to preserve your memories.

The personal experiences you'll find here are from actual Prevagen users. They are not from employees, friends or any party where compensation was offered as an inducement for providing a favorable testimonial. These are real reviews from real people.

•••

Mary remembers names better

I would say I probably noticed a difference within a month of taking Prevagen. That I was able to remember things better. And I wasn't as frustrated with myself, which was great.

•••

Jim improved his memory*

I had such a positive experience from Prevagen that I would urge anybody to at least try it and see if it'll work for them, because it sure helped me.

•••

"Why not try it?"

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It was about 3 weeks when the product began to work for me, and it's just getting better. I think its important to optimally age, there's no such thing as anti-aging, we're all going to age. But for me, this has been optimal.

...

D. The Brain Health Guide, Mark Underwood, February 11, 2016 (Exhibit D)

CHAPTER 1
AMERICA'S STATE OF BRAIN HEALTH

As we age, mild memory problems result in more difficulty in remembering. They also lead to an inability to focus, pay attention or stay on task. With advancing age comes increasing stress that can affect the brain.

...

CHAPTER 10
WHAT IS PREVAGEN?

...

In order to stay healthy, the brain has specific proteins which help support brain cell function. Like other physiological processes in normal aging, the brain's level of these proteins decreases as we grow older. In the progression of normal aging, signs of forgetfulness become more obvious in our 50s. What was once easy to recall, now takes a little longer to retrieve.

How often do these occur? You may want to ask a loved one to help you answer the questions!

1. Forget words you want to use in a conversation.
2. Set items down and then forget where you placed them.
3. Repeat tasks that you already completed previously.
4. Forget details of what you did or what happened to you yesterday.
5. Ask someone the same question twice or telling [sic] the same story.

Prevagen may help you improve your memory.*

Breakthrough Brain Health Supplement*
Prevagen is a safe and effective brain health supplement shown to improve memory.* Prevagen supports brain function by using the protein apoaequorin to supplement the proteins that are diminished as we age.* Supplementing with Prevagen has also shown to support the performance of the brain as demonstrated in cognitive testing. (More on this topic in the next chapter.)*

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• • •

Chapter 11
THE LATEST SCIENCE

• • •

PREVAGEN IMPROVES MEMORY*

In 2010, Quincy Bioscience set out to build on the strong evidence that had been gathered on ability [sic] of apoaequorin to improve memory*

• • •

The goal of the Madison Memory Study was to measure Prevagen's ability to improve brain function using computer software in people experiencing normal age-related mild memory difficulties.*

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• • •

A total of 218 adults ages 40 to 91 years old, were tested at predetermined one-month time intervals and changes on specific assessments of cognitive function were measured at various time points during the study. The final results of the study were very encouraging. The data showed that people taking Prevagen had statistically significant improvement in several areas of memory compared to

baseline and to placebo.* The Prevagen group improved their scores in executive function, learning, memory, and word recall.*

•••

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•••

A Life of Quality

Have you ever heard something, and it made an impression on you? That is verbal learning. The act of remembering is primal. And the ability to summon information previously heard or seen is at our core. Being able to recall (and repeat) something that occurred earlier gives our lives greater meaning and purpose.

An example might be experiencing something someone said -- words from a colleague or an actor in a film. Those words -- anything from something profound and memorable to a joke, made an impression. You wanted to remember what you had just heard so you could relate it to others. Still another example might be hearing of a new book, and wanting to recall its title so you could later find out more. Both exhibit verbal learning, an essential brain activity that helps us retain information.

When the International Shopping Recall List Test was presented in the Madison Memory Study, a short shopping list was read aloud to subjects three times in succession with the participants given the chance to repeat what they could remember from the list after each time. Then the other tests were taken. When completed, testers asked each subject to recall verbally what was on the shopping list. The results were significant. Over the 90-day run of the study, subjects within a normal cognitive range and those with mild to moderate impairment fared well. Both groups had taken Prevagen during the three-month study period.

While little in this world is perfect, research, executed properly, uncovers ways that can improve the quality of our lives as we age. And being able to remember and repeat something verbally to others is an example of that quality. In the Madison Memory Study, the Prevagen arm significantly improved all of the above mentioned areas. For more about the study, see the appendix.

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EPILOGUE
RESEARCHERS DISCOVER "A GIFT FROM THE SEA"

Mark Underwood, President and Co-Founder
Quincy Bioscience

•••

Together with Mike Beaman, my business partner, we have developed a way for this unique jellyfish technology to be used for supporting the brain.*

•••

My goal is to help as many people as we can through the further development of Prevagen, by educating people on brain health, and by providing the public with a supplement that has been shown to work and is safe and scientifically sound.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. [This disclosure refers back to the asterisk on this page. It appears in a box in smaller bold text at the very bottom of the page.]

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E. The Better Memory Show Infomercial (Exhibits E-1 (transcript) and E-2 (video))

ON SCREEN: Teri Barr

Television Investigative Journalist

TERI BARR: Hello, I'm Teri Barr. I've been a writer and television investigative journalist for more than 20 years, reporting on stories that can dramatically impact your health and well-being and the health of the people in your life you love and care about. Now, several years ago, I came across a story about a company doing some research on the brain, and I wanted to share this with you. They discovered a protein in jellyfish and they thought it might have the ability to support your brain and improve your memory. So, our special guest today is going to share with us exactly how this gift from the sea holds the key to improving normal age-related memory problems and so much more. I'm happy to have with us today Mark Underwood. He is a neuroscientist. He is also an author and has been featured in media all across the country talking about this discovery. And he also has a very special personal story to share. Mark, thank you for joining us today.

ON SCREEN: Mark Underwood

President of Quincy Bioscience, Neuroscientist,

Author

MARK UNDERWOOD: Well, thank you, Teri. Memory problems are a big issue.

TERI BARR: Right.

MARK UNDERWOOD: As the baby boomers continue to age, we see more and more people that are struggling with day-to-day activities. They might become forgetful and lose their car keys or their cell phone, but certainly, you know, even some of us, well, we might walk into a room and forget where we're going.

TERI BARR: Mm-hmm.

MARK UNDERWOOD: -- or we're rummaging through the refrigerator and we forget what we're up to. Our research has shed some new light on how to improve these mild memory issues and, hopefully, it will be helpful for all those that are out there watching us today to learn more about how the brain works, how it changes with the aging process and, specifically, how we can use that unique protein found in the jellyfish to help our brains, well, get a little better, help our memory improve, and that's offering a lot of hope to people, those that have already been using Prevagen for some time, to help them with their day-to-day lives and make it a little bit easier.

•••

MARK UNDERWOOD: A large double blind, placebo-controlled trial that we completed that showed great efficacy for Prevagen, showing statistically significant improvements in word recall, in executive function, and also in short term memory.

ON SCREEN: Word Recall

Executive Function

Short-term Memory

•••

ON SCREEN: In a clinical trial participants showed improvement in memory in 90 days. Results published in peer reviewed journal in July 2011.

MARK UNDERWOOD: In the clinical trial, we were showing those benefits after the first month and those continued to improve after the second and third months.

• • •

ON SCREEN: Sue H.

Prevagen User

SUE H.: When I first heard about Prevagen from my neighbor, Jan, I hoped that it would help my middle-aged memory become a little clearer. At work, I multitask all day long and I would find myself standing over somewhere wondering, why did I come back here. I find that a lot less now. Since I started taking Prevagen, I feel like I'm able to stay on task without wavering off and doing three different things, multitasking. I can stay on task and finish my project and it's just easier. We see probably 60 patients in our office a day. The doctor asked several of us if we remembered this certain patient and I was the only one that could come up with her name. They think I'm amazing. They just are amazed at my memory at work. I would tell my friends and relatives that Prevagen is great. I'd recommend it to all of them no matter what age just because of the benefits that I have seen in my focus and memory.

• • •

F. Prevagen Express Bus, Instagram Post Captured on March 31, 2016 (Exhibit F)

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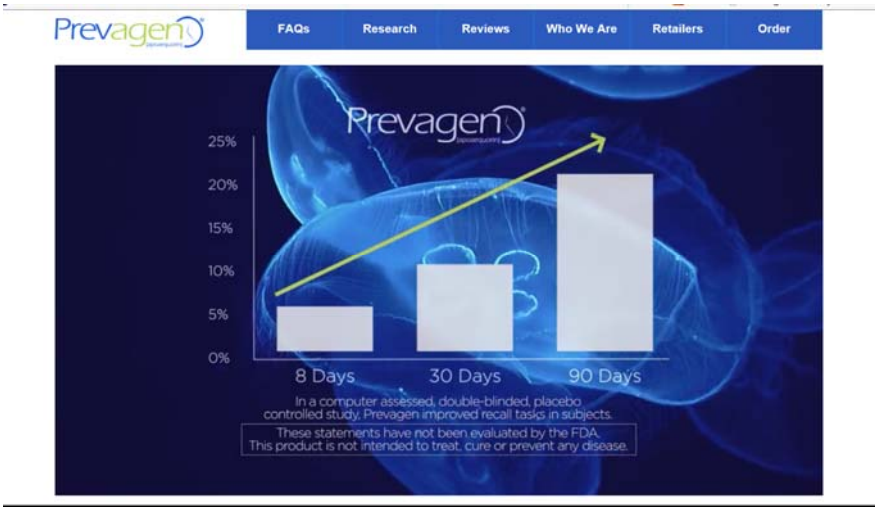
28. To substantiate their claims that Prevagen improves memory, is clinically shown to improve memory, improves memory within 90 days, is clinically shown to improve memory within 90 days, reduces memory problems associated with aging, is clinically shown to reduce memory problems associated with aging, provides other cognitive benefits, and is clinically shown to provide other cognitive benefits, Defendants primarily rely on one double-blind, placebo-controlled human clinical study using objective outcome measures of cognitive function. This study, called the Madison Memory Study, involved 218 subjects taking either 10 milligrams of Prevagen or a placebo. The subjects were assessed on nine computerized cognitive tasks, designed to assess a variety of cognitive skills, including memory and learning, at various intervals over a period of ninety days. The Madison Memory Study failed to show a statistically significant improvement in the treatment group over the placebo group on any of the nine computerized cognitive tasks.

29. After failing to find a treatment effect for the sample as a whole, the researchers conducted more than 30 post hoc analyses of the results, looking at data broken down by several variations of smaller subgroups for each of the nine computerized cognitive tasks. This methodology greatly increases the probability that some statistically significant differences would occur by chance alone. Even so, the vast majority of these post hoc comparisons failed to show statistical significance between the treatment and placebo groups. Given the sheer number of comparisons run and the fact that they were post hoc, the few positive findings on isolated tasks for small subgroups of the study population do not provide reliable evidence of a treatment effect.

30. Nevertheless, Defendants widely touted the Madison Memory Study in their advertising. For example, the chart below appeared in the product labels for the Prevagen Products and Defendants' TV ads and website, prevagen.com. It indicates that a "double-blinded, placebo controlled study" showed dramatic improvement in recall tasks when, in fact, the results for the specific task referenced in the chart showed no statistically significant improvement in subjects taking Prevagen compared to subjects taking a placebo. In addition, Defendants eliminated from the chart one of the four data points in the study – day 60. At day 60, the recall task scores of subjects taking Prevagen declined from day 30, and were slightly worse than the recall task scores of subjects in the placebo group.



31. Defendants' claims that their product improves memory and cognition rely on the theory that the product's dietary protein, apoaequorin, enters the human brain to supplement endogenous proteins that are lost during the natural process of aging. Defendants developed their product and created their marketing campaign based on this theory. Defendants, however, do not have studies showing that orally-administered apoaequorin can cross the human blood brain barrier and therefore do not have evidence that apoaequorin enters the human brain. To the

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contrary, Defendants' safety studies show that apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein.

VIOLATIONS OF THE FTC ACT

32. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices in or affecting commerce."

33. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

34. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics.

35. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Prevagen is either a "food" or "drug" as defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b), (c).

COUNT I

FALSE OR UNSUBSTANTIATED EFFICACY CLAIMS

(By Plaintiff Federal Trade Commission)

36. Through the means described in Paragraphs 19 through 31, Defendants have represented, directly or indirectly, expressly or by implication, that:

A. Prevagen improves memory;

B. Prevagen improves memory within 90 days;

C. Prevagen reduces memory problems associated with aging; and

D. Prevagen provides other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking.

37. The representations set forth in Paragraph 36 are false or misleading, or were not substantiated at the time the representations were made.

38. Therefore, the making of the representations as set forth in Paragraph 36 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT II

FALSE PROOF CLAIMS

(By Plaintiff Federal Trade Commission)

39. Through the means described in Paragraphs 19 through 31, Defendants have represented, directly or indirectly, expressly or by implication, that:

A. Prevagen is clinically shown to improve memory;

B. Prevagen is clinically shown to improve memory in 90 days;

C. Prevagen is clinically shown to reduce memory problems associated with aging; and

D. Prevagen is clinically shown to provide other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking.

40. The representations set forth in Paragraph 39 are false.

41. Therefore, the making of the representations as set forth in Paragraph 39 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

VIOLATIONS OF NEW YORK STATE LAW

COUNT III

REPEATED FRAUDULENT OR ILLEGAL ACTS

(By Plaintiff NYAG)

42. As set forth in Paragraphs 19 through 31 above, which allegations are incorporated as if set forth herein, Defendants have committed acts and practices that constitute repeated and persistent fraudulent and illegal conduct in violation of NY Exec. Law § 63(12), including misrepresenting, directly or indirectly, expressly or by implication, that:

A. Prevagen improves memory;

B. Prevagen is clinically shown to improve memory;

C. Prevagen improves memory within 90 days;

D. Prevagen is clinically shown to improve memory within 90 days;

E. Prevagen reduces memory problems associated with aging;

F. Prevagen is clinically shown to reduce memory problems associated with aging;

G. Prevagen provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking; and

H. Prevagen is clinically shown to provide other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking.

43. The representations set forth in Paragraph 42 are false or misleading, or were not substantiated at the time the representations were made.

COUNT IV

DECEPTIVE ACTS OR PRACTICES AND FALSE ADVERTISING

(By Plaintiff NYAG)

44. As set forth in Paragraphs 19 through 31 above, which allegations are incorporated as if set forth herein, Defendants have committed acts and practices that constitute repeated and persistent fraudulent and illegal conduct and false advertising in violation of NY GBL §§ 349 and 350, including misrepresenting, directly or indirectly, expressly or by implication, that:

A. Prevagen improves memory;

B. Prevagen is clinically shown to improve memory;

C. Prevagen improves memory within 90 days;

D. Prevagen is clinically shown to improve memory within 90 days;

E. Prevagen reduces memory problems associated with aging;

F. Prevagen is clinically shown to reduce memory problems associated with aging;

G. Prevagen provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking; and

H. Prevagen is clinically shown to provide other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking.

45. The representations set forth in Paragraph 44 are false or misleading, or were not substantiated at the time the representations were made.

CONSUMER INJURY

46. Consumers have suffered and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act, NY Exec. Law § 63(12), and NY GBL §§ 349 and 350. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

47. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

48. NY Exec. Law § 63(12) and NY GBL §§ 349 and 350 authorize this Court to issue appropriate orders granting equitable or other appropriate relief for Defendants' violations of NY Exec. Law § 63(12) and NY GBL §§ 349 and 350.

PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and Plaintiff State of New York, pursuant to NY Exec. Law § 63(12) and NY GBL §§349 and 350, and as authorized by the Court's own equitable powers, request that the Court:

A. Enter a permanent injunction to prevent future violations of the FTC Act, the NY Exec. Law, and the NY GBL by Defendants;

B. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, the NY Exec. Law, and the NY GBL, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies;

C. Award civil penalties in an amount up to $5,000 for each violation of NY GBL §§ 349 and 350, pursuant to NY GBL § 350-d; and

D. Award Plaintiffs the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

Dated: January 9, 2017

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company;

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.; and

MICHAEL BEAMAN, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.

Defendants.

Case No. 1:17-cv-00124-LLS

DECLARATION OF GLENN T. GRAHAM

GLENN T. GRAHAM, an attorney duly admitted to practice law before this Court, declares the following to be true under penalty of perjury pursuant to 28 U.S.C. § 1746:

1. I am an associate with the law firm of Kelley Drye & Warren LLP, attorneys for defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc. d/b/a Sugar River Supplements, and Quincy Bioscience Manufacturing, LLC (collectively, "Defendants"). I make this Declaration in support of Defendants' Motion to Dismiss the Complaint pursuant to Rule 12(b)(6).

2. I have attached hereto as Exhibit 1 and true and correct copy of the following document: Kenneth C. Lerner, *Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults*, (Aug. 1, 2016). This document is publicly available on Defendants' website, located at https://www.prevagen.com/research/. A copy of this document is attached hereto for the Court's convenience.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: April 4, 2017
Parisppany, NJ

Glenn T. Graham

Exhibit 1

Clinical Trial Synopsis QB-0011

TITLE:
Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults

SPONSOR:
Quincy Bioscience, LLC

PRINCIPAL INVESTIGATOR:
Kenneth C. Lerner, Quincy Bioscience, LLC

OBJECTIVE:
The primary objective of the Madison Memory Study was to determine whether Prevagen® with apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults

STUDY DATES:
3 December 2009 to 13 April 2011

REPORT DATE:
1 August 2016

INTRODUCTION

Apoaequorin is a protein originally found in a species of jellyfish (1). It is available commercially in a dietary supplement and has been determined to be safe (2) and non-allergenic (3).

Apoaequorin has been shown in laboratory studies to support neuronal cells (4), (5). Based on in vitro and in vivo animal studies (4), (5), (6), (7), we hypothesized that apoaequorin has the potential to enhance memory and cognitive function in humans. Previous work with apoaequorin in aged canines demonstrated cognitive enhancement (7).

STUDY DESIGN

The Madison Memory Study was a randomized, double-blind, placebo-controlled study designed to examine the effect of apoaequorin on cognitive function in older adults. Community dwelling participants were randomized into either the Experimental group (apoaequorin) or Control group (placebo) at a ratio of 3:2. Participants in the Control group received capsules containing only white rice flour. Participants in the Experimental group received capsules containing apoaequorin (10 mg) and white rice flour. Capsules were size and color matched. Participants were instructed to take one (1) capsule daily for the duration of the study.

To segregate participants by their level of self-reported cognitive impairment, a Baseline participant score was acquired using the AD8 screening tool. The AD8 is a brief (8-question) screening tool that was developed to differentiate adults facing normal cognitive aging from those with early signs of dementia (8), (9), (10). In this study, an AD8 score of 2 was used as a cut-off value to discriminate between those people who are cognitively normal or very mildly impaired (AD8 0-2) versus those with higher levels of impairment (AD8 3-8). Because Prevagen is a dietary supplement intended for healthy, non-demented individuals, results from the AD8 0-1 and AD8 0-2 subgroups are the most relevant to the efficacy of the product.

Quantitative, computerized cognitive tests were employed to examine the effect of apoaequorin over time and compared to placebo. The tests used in this study are part of the CogState Research battery and are adaptations of standard neuropsychological tests. CogState was selected for this study because its tests are brief, repeatable, and have shown little or no practice effects (11), (12), (13).

Nine CogState tests were used in this study: the International Shopping List (ISL), International Shopping List-Delayed Recall (ISRL), Groton Maze Learning (GML), Groton Maze Recall (GMR), Detection (DET), Identification (IDN), One Card Learning (OCL), One Back (ONB), and Two Back (TWOB) (Table 1).

Table 1 Cognitive Measurement Tests

Task	Cognitive Domain Measured
International Shopping List (ISL)	Verbal Learning
International Shopping List - Delayed Recall (ISRL)	Memory
Groton Maze Learning (GML)	Executive Function
Groton Maze Learning - Delayed Recall (GMR)	Memory
Detection (DET)	Psychomotor Function
Identification (IDN)	Attention
One Card Learning (OCL)	Visual Learning
One Back (ONB)	Working Memory
Two Back (TWOB)	Working Memory

Trained proctors administered the CogState tests. Participants completed testing sessions on five (5) occasions (Day(s) 0, 8, 30, 60, & 90). The primary efficacy variable was change from Day 0 (Baseline) to Day 90 on the CogState tests.

The ISL and the ISRL tests measure changes in verbal learning and working memory (13, 14). Verbal learning is the cognitive function associated with memorization and retention of a list of words. However, verbal learning is not solely the memorization of a list of words. It refers to the ability to learn information verbally (15). Verbal working memory is the ability to keep instructions in working memory and use them to perform a task. The ability to use verbal working memory is necessary to perform a task that is preceded by verbal instructions.

The ISL is a 12-word, three-trial, verbal list-learning test that is similar to other verbal list assessments. In the ISL, the presentation of stimuli and the recording of responses are facilitated by a trained proctor and recorded by the computer. Each 12-word list that is used is generated by the software and presented in a random order. The list is presented three (3) times to the participants. The ISL has good sensitivity to impaired/altered verbal memory. The ISRL is a repetition of the ISL list presented approximately 25 minutes after the initial three (3) trials. The ISRL measures verbal learning and delayed memory/recall.

The primary outcome measure for the ISL is the change in the total number of shopping list words participants are able to remember during three (3) iterations of the test. The primary outcome measure for the ISRL is the number of words recalled from the shopping list presented approximately 25 minutes earlier. For both tests, higher scores indicate better performance.

The GML and the GMR tests assess executive function and visual-spatial memory/problem solving (16). Executive function is comprised of high-level cognitive processes that help individuals complete complicated tasks and accomplish goals. Executive function refers to mental skills that are coordinated in the frontal lobe and includes the ability to manage time and attention, switch focus, plan and organize, remember details, and integrate past experiences. Compromised executive functioning has been strongly linked to the decreased ability to perform Instrumental Activities of Daily Living (IADL) (17).

In the GML and GMR, a 10x10 grid of tiles is presented on the computer screen. Within this grid is a 28-step hidden pathway. Starting at the top, left-hand corner, subjects are instructed to move through the maze one step at a time in order to learn the correct pathway. The last tile in the maze is in the lower, right hand corner. Subjects are guided by audio and visual feedback. Subjects completed the GML five (5) times in succession during each testing session. The GMR repeats the same hidden maze seen earlier in the testing session. This round is presented approximately 30 minutes after the first five (5) rounds. The primary measure for both the GML and the GMR is the total number of errors, with lower scores indicating better performance.

The DET test is a simple reaction time test that measures psychomotor speed. The participant must press the "Yes" key as quickly as possible when a card presented in the center of the screen turns face-up. The test ends when 35 correct trials are recorded. Mean speed of performance for correct responses is the outcome measure. A lower score indicates better performance.

The IDN test is a choice reaction time test that measures visual attention. The participant must press the "Yes" key as quickly as possible when the presented card is red or "No" if it is black. The test ends when 30 correct trials are recorded. Mean speed of performance for correct responses is the outcome measure. A lower score indicates better performance.

The OCL test assesses visual attention and recognition memory. Participants are asked to respond "Yes" if the face-up card appeared previously in the test

and "No" if it did not. Six (6) cards were repeated in a total of 42 cards. Mean accuracy is the outcome measure. A higher score indicates better performance.

The ONB test assesses visual attention and working memory. Participants are asked to respond "Yes" if the face-up card is exactly the same as the card that immediately preceded it or "No" if it is not. The test ends when 30 correct trials are recorded. Mean speed of performance for correct responses is the outcome measure.

The TWOB test assesses visual attention and delayed recall. Participants are asked to respond "Yes" if the face-up card is exactly the same as the card that was shown two cards earlier. The test ends when 30 correct trials are recorded. Mean speed of performance for correct responses is the outcome measure.

MATERIAL

Participants in the Control group received capsules containing only white rice flour. Participants in the Experimental group received capsules containing apoaequorin (10 mg) and white rice flour.

STUDY SAMPLE

During the screening phase participants were interviewed about their medical history and physical activity. Eligibility criteria included the following: (1) healthy males and females not excluded by predetermined exclusion criteria; (2) age between 40 to 95 at Baseline (Day 0); (3) concerns related to memory issues; and (4) ability to comply with the study protocol and complete periodic computerized cognitive tests. Individuals were excluded if they had: (1) a history of uncontrolled hypertension; (2) untreated psychotic or major depressive disorder; (3) a significant neurological disease; or (4) the inability to adhere to the study protocol or complete periodic computerized cognitive tests.

A total of 218 participants, ages 40 to 91, with self-reported memory concerns were enrolled in the study. Two hundred and eleven (211) participants completed the study.

STATISTICAL ANALYSIS

The principal aim of the analysis was to compare the effects of apoaequorin (10 mg) versus placebo over time on the outcomes of the CogState Research tests. Data analyses were performed on the intention-to-treat population, which included all randomized subjects.

To assess whether sample selection bias occurred, unpaired t-tests (normal variables) or Wilcoxon ranked sum tests (skewed variables) were performed on the pre-treatment (Baseline) values for the Experimental and Control groups. Paired t-tests or Wilcoxon signed rank tests were also used to examine changes from Baseline to each follow-up visit. A mixed model repeated-measures analysis of covariance was employed to compare the treatment effects between the two groups. This methodology accommodated longitudinal data with repeated measures, the prevention of false positive associations due to interaction terms, and loss minimization of data due to missing observations. The model included the Experimental group, time, and the interaction term between the two (group x time). The Baseline value of each outcome variable was added to the model in light of the possible effect of Baseline differences on the results. Once a model was selected and fitted to the data for a particular outcome variable, the interrelationships between group, time, and Baseline were assessed.

The results were expressed as mean and standard error of the mean (SEM) with a value $p \leq 0.05$ (2-tailed) as a criterion for statistical significance. Statistical analyses were performed using SAS 9.3 software (SAS Institute, Cary, North Carolina).

Participants were segregated into analysis groups based on self-reported levels of cognitive impairment as measured by the AD8 screening tool. Because Prevagen is a dietary supplement intended for healthy, non-demented individuals, particular focus was placed on the AD8 0-1 and 0-2 groups, which included only those individuals with AD8 scores suggesting normal cognitive aging or very mild impairment.

RESULTS

While no statistically significant results were observed over the entire study population, there were statistically significant results in the AD8 0-1 and AD8 0-2 subgroups. These subgroups contain individuals with either minimal or no cognitive impairment, and are the appropriate population for a dietary supplement intended to support people with mild memory loss associated with aging.

Table 2 shows participants' characteristics and Baseline test outcomes. In the AD8 0-2 and AD8 0-1 subgroups, no statistically significant differences were noted in Baseline values between the Experimental and Control groups in any of the nine variables. The randomization was successful.

Table 2 Characteristics and Test Outcomes of the Participants at Baseline

	AD8 0-2			AD8 0-1		
	Placebo n=40	Apoaequorin n = 60	P Value	Placebo n = 24	Apoaequorin n = 37	P Value
Age	67.45 + 10.30	64.23 + 10.65	0.137	69.17 + 8.391	64.78 + 10.99	0.130
AD8	1.150 + 0.802	1.017 + 0.873	0.461	0.583 + 0.504	0.405 + 0.498	0.180
ISL	24.45 ± 4.075	25.01 ± 5.434	0.567	24.62 ± 3.499	24.48 ± 6.162	0.888
ISRL	8.275 ± 2.385	8.762 ± 2.336	0.336	8.208 ± 2.449	8.702 ± 2.654	0.469
GML	60.37 ± 21.08	58.59 ± 23.45	0.648	61.83 ± 21.54	57.64 ± 18.97	0.570
GMR	9.400 ± 5.424	8.898 ± 4.470	0.903	9.208 ± 4.211	9.324 ± 4.870	0.894
DET	2.500 ± 0.081	2.534 ± 0.104	0.089	2.503 ± 0.066	2.543 ± 0.095	0.077
IDN	2.726 ± 0.068	2.729 ± 0.072	0.913	2.733 ± 0.066	2.725 ± 0.069	0.624
OCL	1.005 ± 0.113	1.013 ± 0.107	0.583	1.016 ± 0.103	1.017 ± 0.103	0.972
ONB	1.298 ± 0.185	1.356 ± 0.163	0.188	1.313 ± 0.145	1.356 ± 0.156	0.298
TWOB	1.223 ± 0.164	1.251 ± 0.141	0.306	1.220 ± 0.168	1.244 ± 0.148	0.564

Notes on Table 2
1 All values are described with mean ± standard deviation (SD).
2 P value is based on unpaired t-test (normal variables) or a Wilcoxon ranked sum test (skewed variables).

Table 3 and 4 list the mean values and SD of outcomes on Day 0 and Day 90 for the AD8 0-1 AD8 0-2 subgroups, respectively. Within group p values and p values from the mixed model analysis are also reported.

Table 3 The Score Differences in the Two Groups Before and After Treatment (AD8 0-1)

	Placebo		Within p	Apoaequorin		Within p	Between Group P value			
Tasks	Day 0	Day 90	value	Day 0	Day 90	value	Group	Time	Group x Time	Base
ISL	24.62 ± 3.499	25.19 ± 5.163	0.373	24.48 ± 6.162	27.25 ± 5.106	0.002*	0.125	0.040*	0.279	<.0001*
ISRL	8.208 ± 2.449	8.904 ± 2.947	0.030*	8.702 ± 2.654	9.277 ± 2.614	0.091	0.704	0.134	0.897	<.0001*
GML	61.83 ± 21.54	51.00 ± 21.54	0.003*	57.64 ± 18.97	44.58 ± 13.69	<0.0001*	0.103	<.0001*	0.491	<.0001*
GMR	9.208 ± 4.211	8.809 ± 5.182	0.296	9.324 ± 4.870	6.444 ± 3.691	0.000*	0.011*	0.065	0.078	<.0001*
DET	2.503 ± 0.066	2.557 ± 0.096	0.005*	2.543 ± 0.095	2.530 ± 0.082	0.561	0.015*	0.146	0.021*	<.0001*
IDN	2.733 ± 0.066	2.727 ± 0.059	0.965	2.725 ± 0.069	2.723 ± 0.059	0.854	0.246	0.979	0.460	<.0001*
OCL	1.016 ± 0.103	1.018 ± 0.119	0.836	1.017 ± 0.103	1.049 ± 0.093	0.057	0.010*	0.330	0.193	<.0001*
ONB	1.313 ± 0.145	1.404 ± 0.160	0.015*	1.356 ± 0.156	1.397 ± 0.145	0.214	0.220	0.013*	0.388	<.0001*
TWOB	1.220 ± 0.168	1.321 ± 0.157	0.021	1.244 ± 0.148	1.312 ± 0.134	0.019*	0.747	0.004*	0.474	<.0001*

Notes on Table 3
1 Time is the number of visits since the initial Baseline visit and was coded as a categorical variable.

Table 4 The Score Differences in the Two Groups Before and After Treatment (AD8 0-2)

	Placebo		Within p	Apoaequorin		Within p	Between Group P value			
Tasks	Day 0	Day 90	value	Day 0	Day 90	value	Group	Time	Group x Time	Base
ISL	24.45 ± 4.075	25.50 ± 5.474	0.090	25.01 ± 5.434	27.68 ± 4.634	<0.0001*	0.324	0.000*	0.039*	<.0001*
ISRL	8.275 ± 2.385	9.000 ± 2.908	0.012*	8.762 ± 2.336	9.482 ± 2.400	0.002*	0.465	0.015*	0.703	<.0001*
GML	60.37 ± 21.08	50.02 ± 22.43	0.000*	58.59 ± 23.45	46.46 ± 18.78	<0.0001*	0.040*	<.0001*	0.463	<.0001*
GMR	9.400 ± 5.424	8.861 ± 5.938	0.229	8.898 ± 4.470	7.017 ± 4.722	0.001*	0.107	0.092	0.367	<.0001*
DET	2.500 ± 0.081	2.537 ± 0.099	0.045*	2.534 ± 0.104	2.533 ± 0.100	0.675	0.250	0.165	0.365	<.0001*
IDN	2.726 ± 0.068	2.732 ± 0.064	0.267	2.729 ± 0.072	2.725 ± 0.061	0.815	0.037*	0.780	0.108	<.0001*
OCL	1.005 ± 0.113	1.018 ± 0.121	0.292	1.013 ± 0.107	1.041 ± 0.100	0.046*	0.020*	0.437	0.357	<.0001*
ONB	1.298 ± 0.185	1.421 ± 0.156	<.0001*	1.356 ± 0.163	1.397 ± 0.140	0.081	0.944	0.000*	0.223	<.0001*
TWOB	1.223 ± 0.164	1.317 ± 0.176	0.002*	1.251 ± 0.114	1.302 ± 0.127	0.028*	0.934	0.000*	0.290	<.0001*

Notes on Table 4
1 Time is the number of visits since the initial Baseline visit and was coded as a categorical variable.

International Shopping List and International Shopping List-Delayed Recall

Figure 1 shows the average percentage change in ISL scores from Baseline to each visit in participants with AD8 scores of 0-1. The Experimental group demonstrated an 11.29% increase in the number of correct responses, while the Control group exhibited a 2.30% improvement. As compared to Baseline, a statistically significant difference was observed in the Experimental group (p=0.002), but not the Control group (p=0.373). A trend towards significance was shown in comparing the Experimental group's results to the Control group's results (p=0.125).

Figure 2 shows the average percentage change in ISL scores from Baseline to each visit in participants with AD8 scores of 0-2. The Experimental group showed a 10.68% increase in the number of correct responses, while the Control group showed a 4.29% increase. Compared to Baseline, the number of correct responses was significantly increased in the Experimental group (p<0.0001), but not in the Control group (p=0.090). The two groups tended to show a group difference of greater magnitude. Nonetheless, a significant difference between the Experimental and Control groups was not observed (p=0.324). This may be the result of a score reduction that occurred at visit 2 in the Experimental group.

As compared to Baseline, both groups showed a statistically significant or nearly significant increase in ISRL scores in participants with AD8 scores of 0-2 and participants with AD8 scores of 0-1. Significant differences between the Experimental and Control groups were not observed.

Figure 1: Percentage Change of ISL (AD8 0-1)

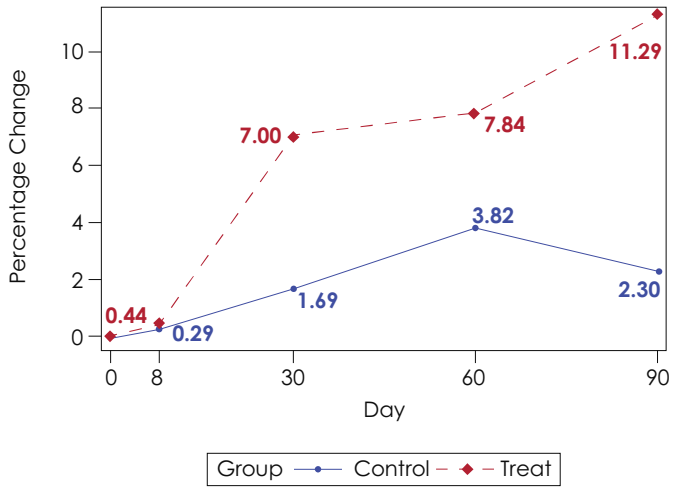
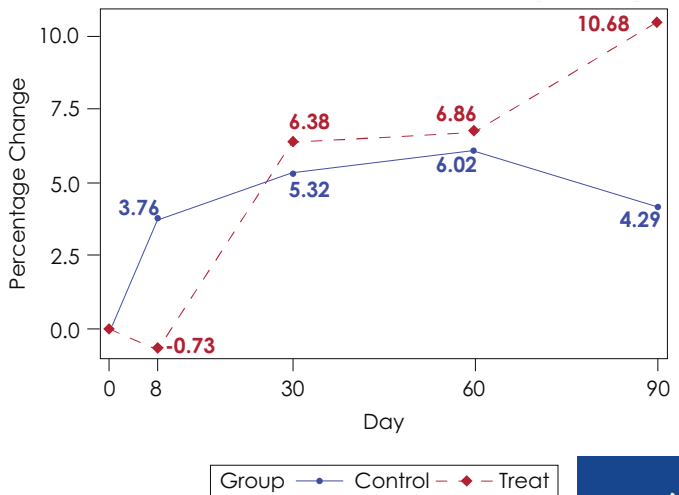


Figure 2: Percentage Change of ISL (AD8 0-2)



Groton Maze Learning

Figure 3 shows the average percentage change in GML scores from Baseline to each visit in participants with AD8 scores of 0-1. As compared to Baseline, both groups showed statistically significant reductions in total errors (Experimental p<0.0001, Control p=0.003). There was a trend towards significance in comparing the results from the Experimental group to the Control group (p=0.103).

Figure 4 shows the average percentage change in GML scores from Baseline to each visit in participants with AD8 scores of 0-2. The Experimental group demonstrated a 20.70% reduction in the number of moves required to traverse a 10x10 maze, while the Control group exhibited a 17.14% reduction. As compared to Baseline, both groups experienced a statistically significant reduction in the number of moves required (Experimental p<0.0001, Control p=0.0002). The Experimental group's results were statistically significant as compared to the Control group (p=0.0400).

Groton Maze Recall

Figure 5 shows the average percentage change in GMR scores from Baseline to each visit in participants with AD8 scores of 0-1. The Experimental group required 30.89% fewer moves to complete the maze between Days 0 and 90. The Control group experienced a 4.33% reduction. Compared to Baseline, a statistically significant change was observed in the Experimental group (p=0.000), but not the Control group (p=0.296). The Experimental group's results were statistically significant compared to the Control group (p=0.011).

Figure 3: Percentage Change of GML (AD8 0-1)

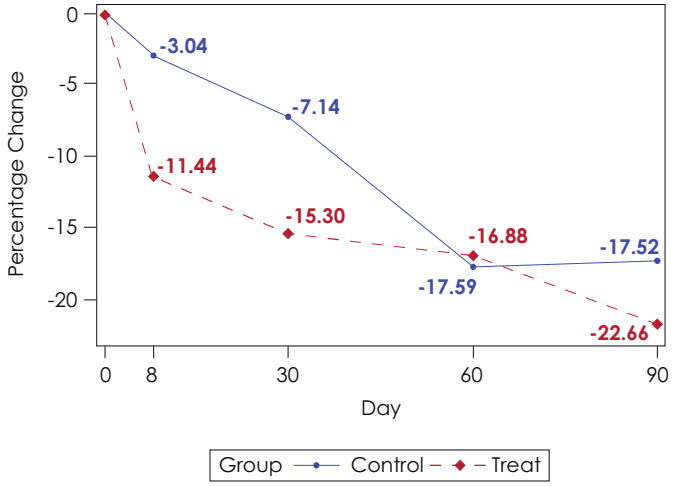


Figure 4: Percentage Change of GML (AD8 0-2)

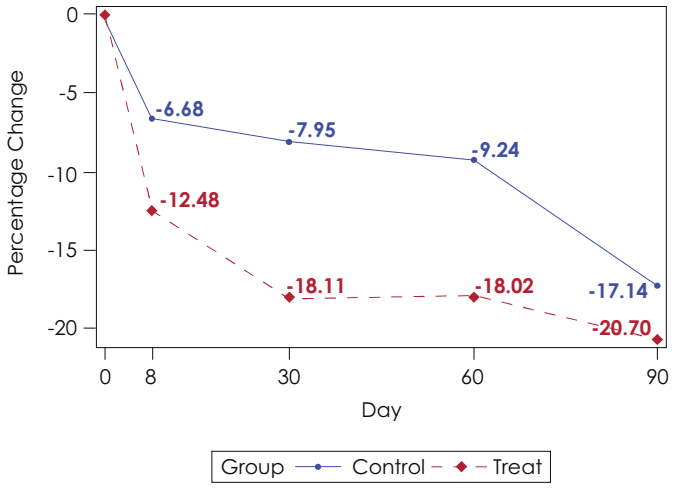


Figure 5: Percentage Change of GMR (AD8 0-1)

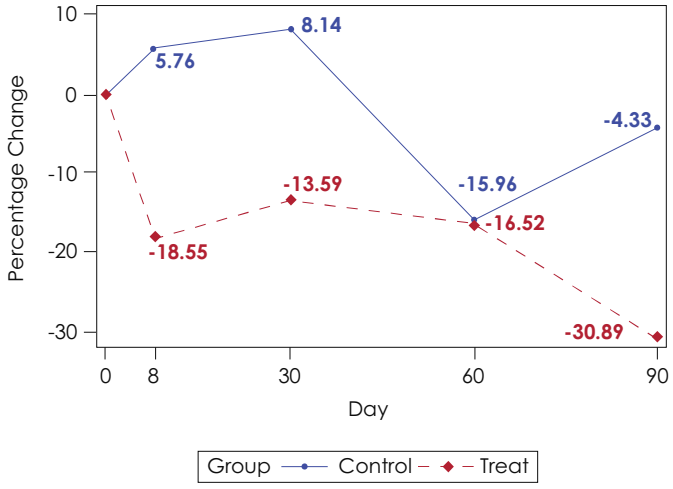
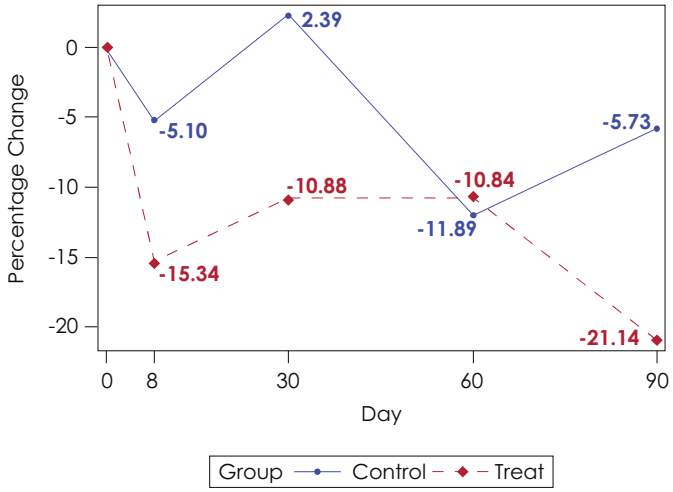


Figure 6 shows the average percentage change in GMR scores from Baseline to each visit in participants with AD8 scores of 0-2. The total number of moves required to traverse the maze in the Experimental group decreased by 21.14% between Baseline and Day 90, compared to only a 5.73% decrease in the Control group. As compared to Baseline, a statistically significant difference was shown in the Experimental group (p =0.001), but not the Control group (p=0.229). The Control group showed an initial decrease of magnitude related to Baseline value followed by a regain in the third visit. There was a trend toward significance in the total number of errors in the Experimental group as compared to the Control group (p=0.107).

Figure 6: Percentage Change of GMR (AD8 0-2)



Detection and Identification

Figure 7 shows the average percentage change in DET scores from Baseline to each visit in participants with AD8 scores of 0-1. A statistically significant difference was shown in the Experimental group as compared to the Control group (p=0.015). For the participants with AD8 scores of 0-2, the Experimental group outperformed the Control group at all post intervention visits, but did not reach the significance level (p=0.250).

Figure 7: Percentage Change of DET (AD8 0-1)

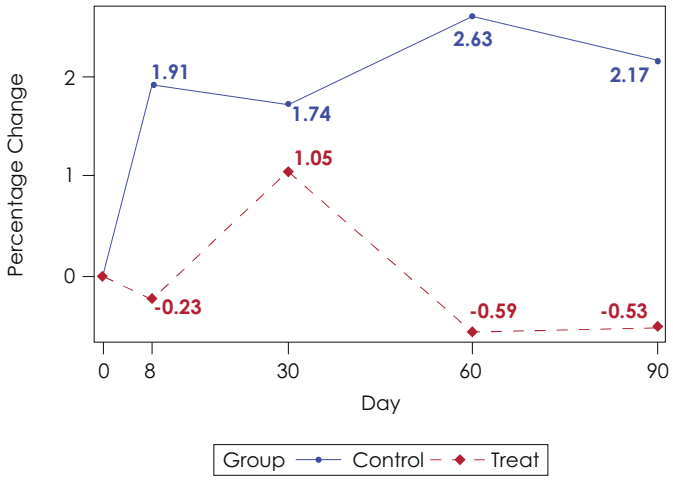
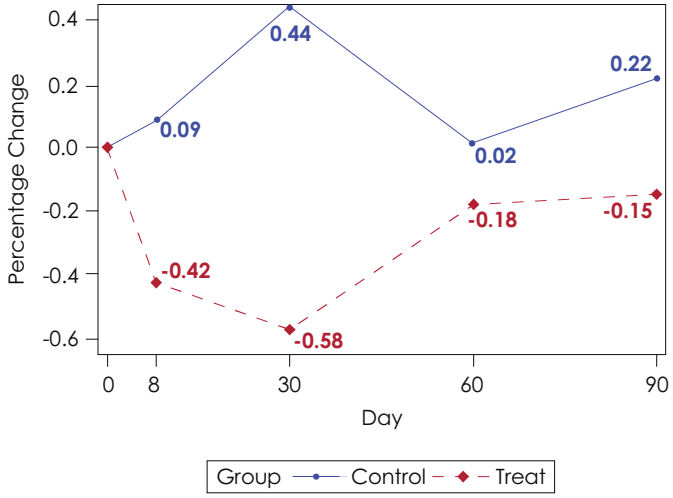


Figure 8 shows the average percentage change in IDN scores from Baseline to each visit in participants with AD8 scores of 0-2. The IDN results showed a statistically significant difference between the two groups (p=0.037). For participants with AD8 scores of 0-1, the between group differences were not statistically significant (p=0.246).

Figure 8: Percentage Change of IDN (AD8 0-2)



One Card Learning

Figure 9 shows the average percentage change in OCL scores from Baseline to each visit in participants with AD8 scores of 0-1. The Experimental group experienced a 3.164% change as compared to a 0.245% change in the Control group. Compared to Baseline, a nearly statistically significant difference was observed in the Experimental group (p=0.057), but not the Control group (p=0.836). The difference between the two groups was statistically significant (p=0.010).

Figure 10 shows the average percentage change in OCL scores from Baseline to each visit in participants with AD8 scores of 0-2. Compared to Baseline, a significant difference was seen in the Experimental group (p=0.046), but not the Control group (p=0.292). A statistically significant difference was observed between the groups (p =0.020).

Figure 9: Percentage Change of OCL (AD8 0-1)

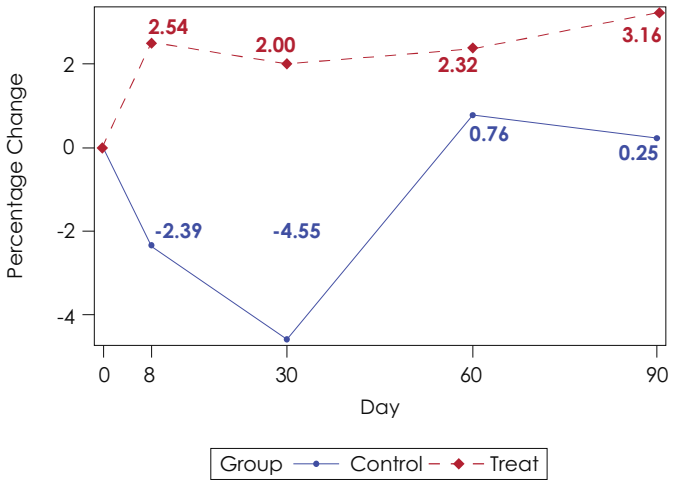
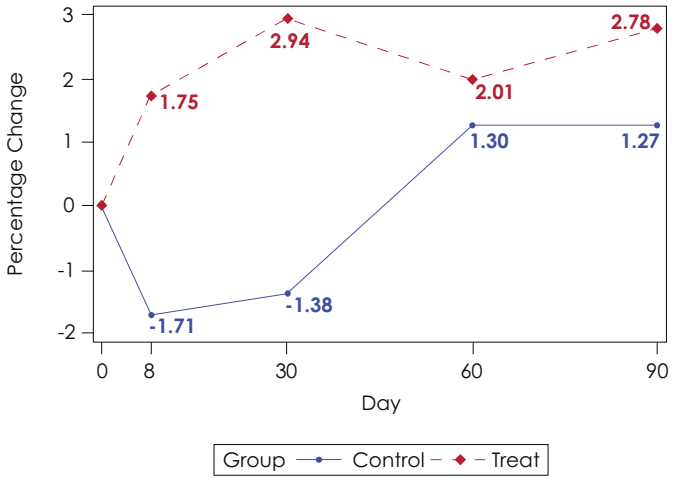


Figure 10: Percentage Change of OCL (AD8 0-2)



One Back and Two Back

In participants with AD8 scores of 0-1 and 0-2, significant differences between the Experimental and Control groups were not observed on either the One Back or the Two Back tests.

Adverse Events

The Experimental and Control substances were very well tolerated. Two participants experienced adverse events during the study. Each group had a single adverse event, and there were no serious adverse events (SAEs) in the study.

Discussion

This study was designed to examine the effect of Prevagen® on cognitive function in a study population of community dwelling, older adults with self-reported cognitive difficulties or concerns. Changes in cognitive function were quantitatively assessed using tests from the CogState Research battery.

Participants in the Experimental group with AD8 scores of 0-1 experienced statistically significant improvements, as compared to the Control group, on the following tests: GMR (p=0.011), DET (p=0.015), and OCL (p=0.010). These participants also experienced trends toward statistical significance on the GML and ISL tests (p=0.103, p=0.125). Participants in the Experimental group with AD8 scores of 0-2 experienced statistically significant improvements, as compared to Control group participants, on the following tests: GML (p=0.040), IDN (p=0.037), and OCL (p=0.02). These participants also experienced a trend toward significance on the GMR test (p=0.107). These data support the hypothesis that oral supplementation with Prevagen supports cognitive function in healthy, non-demented individuals.

Conclusion

Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either normal cognitive aging or very mild impairment, as determined by AD8 screening.

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AO 88B (Rev. 06/09) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

Southern District of New York

Federal Trade Commission, et al.
Plaintiff
v.
Quincy Bioscience Holding Company, Inc., et al.
Defendant

Civil Action No. 1:17-cv-00124-LLS

(If the action is pending in another district, state where:

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Georgetown Economic Services, LLC, c/o Corporation Service Co., 1090 Vermont Ave., NW, Washington, DC 20005

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material: See Attachment A.

Place:	Date and Time:
Federal Trade Commission, attn: William Ducklow 600 Pennsylvania Ave., NW; Mail Drop CC-10528; Washington, DC 20580	01/03/2020 5:00 pm

❒ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 12/11/2019

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

s/ Michelle Rusk
Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing *(name of party)* Federal Trade Commission, who issues or requests this subpoena, are:

Michelle Rusk; FTC; 600 Pennsylvania Ave, NW; CC-10528; Washington, DC 20580; 202-326-3148; mrusk@ftc.gov

Civil Action No. 1:17-cv-00124-LLS

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

ATTACHMENT A

SUBPOENA FOR DOCUMENTS TO GEORGETOWN ECONOMIC SERVICES, LLC

DEFINITIONS

1. "Company" means Georgetown Economic Services, LLC, its wholly or partially owned subsidiaries, affiliates, and all directors, officers, employees, and partners.

2. "Defendants" means Mark Underwood and Quincy Bioscience Holding Co., Inc., Quincy Bioscience, LLC, Prevagen, Inc., doing business as Sugar River Supplements, Quincy Bioscience Manufacturing, LLC, and their corporate parents, wholly and partially owned subsidiaries, and affiliates, and all directors, officers, employees, and partners.

3. "Document" is defined to be synonymous in meaning and equal in scope to the usage of the term "documents or electronically stored information" in Fed. R. Civ. P. 34(a)(1)(A). **A draft or non-identical copy is a separate document within the meaning of this term.**

4. "Concerning" means relating to, referring to, describing, evidencing or constituting.

5. "Madison Memory Study" means the human clinical study conducted by Defendants in which subjects took either 10 milligrams of apoaequorin or a placebo and were tested at several intervals on cognitive tasks selected from the CogState Research Battery. The Madison Memory Study also includes any analysis of data or results conducted by Georgetown Economic Services, LLC or Dr. J. Howard Beales, III, for this human clinical study.

6. The terms "all," "any," and "each" shall each be construed as encompassing any and all.

7. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

8. The use of the singular form of any word includes the plural and vice versa.

DOCUMENTS REQUESTED

1. All documents concerning the scope of work to be performed, services to be provided, or compensation to be provided for work performed by the Company with regard to the Madison Memory Study.

2. Concerning the Madison Memory Study, all documents concerning any statistical analysis of any data, including but not limited to any pretest analysis, intent-to-treat

analysis, within-group or between-group analysis, subgroup analysis, supra-group analysis, re-analysis, post-hoc analysis, or seemingly unrelated regression (SUR) analysis, including but not limited to:

a. All reports, summaries, articles, write-ups, posters, presentations, data tables, or other accounts of the results of such analyses, and drafts of such documents reviewed by Defendants or any other individual or entity;

b. All documents relating to randomization; instructions, including but not limited to oral instructions to participants; subject compliance; dropouts; or dropout rates;

c. All statistical analysis plans, clinical agreements, reports, manuscripts, presentations, abstracts, or meeting notes or minutes, including any amendments, prepared by any individual or entity;

d. All draft, interim, or final data summaries, whether in chart, table, or any other form, including but not limited to baseline and outcome measurements for all enrolled subjects;

e. All data collected from enrolled participants, including but not limited to any participants who did not complete the Madison Memory Study; source documents for such data; and any case report forms;

f. All documents concerning collection and coding of the results of all tests administered on each subject; and

g. All other documents not explicitly referenced herein used to analyze or present the results of the Madison Memory Study.

3. Concerning the Madison Memory Study, all documents related to the design, protocol, and recruitment of subjects, including but not limited to any documents evidencing any

inclusion or exclusion criteria for participation in the study, whether related to subjects' AD-8 scores or otherwise.

4. All communications with any outside entity or person concerning the Madison Memory Study (including but not limited to any analyses of results or data of such study), including but not limited to communications with:

a. Any Defendant;

b. Michael Beaman;

c. CogState Ltd.;

d. Any person retained by, consulted by, or working with any Defendant, including but not limited to:

i. Dr. J. Howard Beales, III;

ii. Dr. David L. Katz;

iii. Dr. Josh Levitt;

iv. Dr. Mindy S. Kurzer;

v. Dr. David H. Schwarz;

vi. Dr. Giovanni Ciavarri;

vii. Dr. Dominik Alexander;

viii. Dr. Robert Krikorian;

ix. Dr. Cedric Annweiler;

x. Dr. Paul B. Pencharz;

xi. Dr. Richard E. Goodman;

xii. Dr. Michael Pezzone;

xiii. Dr. Brian Spencer; and

xiv. Dr. William Bisordi

5. All documents relating to any other human clinical study commenced, discontinued, or completed by or on behalf of any Defendant involving apoaequorin or any product containing apoaequorin, including but not limited to any analysis of any data or results from any such study.

INSTRUCTIONS

As indicated in the subpoena form, the Company should send copies of all responsive documents to William Ducklow, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Mail Drop CC-10528, Washington, D.C., 20580. Because postal delivery to the FTC is subject to delay due to heightened security precautions, please use a courier service such as Federal Express or UPS. The FTC can also facilitate secure electronic transfer of the documents. Please contact William Ducklow at wducklow@ftc.gov to make arrangements to transfer the data electronically.

Attachment B
Federal Trade Commission - Bureau of Consumer Protection
Production Requirements (Revised August 2019)

In producing information to the FTC, comply with the following requirements, unless the FTC agrees otherwise. If you have questions about these requirements, please contact FTC counsel before production.

Production Format

1. **General Format**: Provide load-ready electronic productions with:

    a. A delimited data load file (.DAT) containing a line for every document, unique id number for every document (DocID), metadata fields, and native file links where applicable;

    b. A document level text file, named for the DocID, containing the text of each produced document; and

    c. An Opticon image load file (.OPT) containing a line for every image file, where applicable.

2. **Electronically Stored Information (ESI)**: Documents stored in electronic format in the ordinary course of business must be produced in the following format:

    a. For ESI other than the categories below, submit in native format. Include document level extracted text or Optical Character Recognition (OCR), all metadata, and corresponding image renderings converted to Group IV, 300 DPI, single-page TIFF (or color JPEG images when necessary to interpret the contents or render them intelligible).

    b. For Microsoft Excel, Access, or PowerPoint files, submit in native format with extracted text and metadata. Data compilations in Excel spreadsheets or delimited text formats must contain all underlying data, formulas, and algorithms without redaction.

    c. For other spreadsheet, database, presentation, or multimedia formats; instant messages; or proprietary applications, discuss the production format with FTC counsel.

3. **Hard Copy Documents**: Documents stored in hard copy in the ordinary course of business must be scanned and submitted as 300 DPI single page TIFFs (or color JPEGs when necessary to interpret the contents or render them intelligible), with corresponding document-level OCR text and logical document determination in an accompanying load file.

4. **Document Identification**: Provide a unique DocID for each hard copy or electronic document, consisting of a prefix and a consistent number of numerals using leading zeros. Do not use a space to separate the prefix from numbers.

5. **Attachments**: Preserve the parent/child relationship by producing attachments as separate documents, numbering them consecutively to the parent email, and including a reference to all attachments.

6. **Metadata Production**: For each document submitted electronically, include the standard metadata fields listed below in a standard delimited data load file. The first line of the data load file shall include the field names. Submit date and time data in separate fields. Use these standard Concordance delimiters in delimited data load files:

Description	Symbol	ASCII Character
Field Separator	¶	20
Quote Character	Þ	254
Multi Entry delimiter	®	174
<Return> Value in data	~	126

7. **De-duplication**: Do not use de-duplication or email threading software without FTC approval.

8. **Password-Protected Files**: Remove passwords prior to production. If password removal is not possible, provide the original and production filenames and the passwords, under separate cover.

Producing Data to the FTC

1. Prior to production, scan all data and media for viruses and confirm they are virus-free.

2. For productions smaller than 50 GB, submit data electronically using the FTC's secure file transfer protocol. Contact FTC counsel for instructions. **The FTC cannot accept files via Dropbox, Google Drive, OneDrive, or other third-party file transfer sites**.

3. If you submit data using physical media:

    a. Use only CDs, DVDs, flash drives, or hard drives. Format the media for use with Windows 7;

    b. Use data encryption to protect any Sensitive Personally Identifiable Information or Sensitive Health Information (as defined in the instructions), and provide passwords in advance of delivery, under separate cover; and

    c. Use a courier service (e.g., Federal Express, UPS) because heightened security measures delay postal delivery.

4. Provide a transmittal letter with each production that includes:

    a. Production volume name (e.g., Volume 1) and date of production;

    b. Numeric DocID range of all documents in the production, and any gaps in the DocID range; and

    c. List of custodians and the DocID range for each custodian.

Required Fields for Metadata Load File

FIELD NAME	FIELD DESCRIPTION	FIELD VALUE EXAMPLE[1]
BEGDOC	Bates number assigned to the first page of the document.	ABC0001
ENDDOC	Bates number assigned to the last page of the document.	ABC0002
BEGATTACH	Bates number assigned to the first page of the parent document in a document family (*i.e.*, should be the same as BEGDOC of the parent document, or PARENTDOC).	ABC0001
ENDATTACH	Bates number assigned to the last page of the last child document in a family (*i.e.*, should be the same as ENDDOC of the last child document).	ABC0008
PARENTDOC	BEGDOC of parent document.	ABC0001
CHILDDOCS	List of BEGDOCs of all child documents, delimited by ";" when field has multiple values.	ABC0002; ABC0003; ABC0004…
COMMENTS	Additional document comments, such as passwords for encrypted files.	
NATIVEFILE	Relative file path of the native file on the production media.	.\Native_File\Folder\...\BEGDOC.ext
TEXTFILE	Relative file path of the plain text file on the production media.	.\Text_Folder\Folder\...\BEGDOC.txt
SOURCE	For scanned paper records this should be a description of the physical location of the original paper record. For loose electronic files this should be the name of the file server or workstation where the files were gathered.	Company Name, Department Name, Location, Box Number…
CUSTODIAN	Owner of the document or file.	Firstname Lastname, Lastname, Firstname, User Name; Company Name, Department Name...
FROM	Sender of the email.	Firstname Lastname < FLastname @domain >

[1] Examples represent possible values and not required format unless the field format is specified in Attachment 1.

TO	All to: members or recipients, delimited by ";" when field has multiple values.	Firstname Lastname < FLastname @domain >; Firstname Lastname < FLastname @domain >; …
CC	All cc: members, delimited by ";" when field has multiple values.	Firstname Lastname < FLastname @domain >; Firstname Lastname < FLastname @domain >; …
BCC	All bcc: members, delimited by ";" when field has multiple values	Firstname Lastname < FLastname @domain >; Firstname Lastname < FLastname @domain >; …
SUBJECT	Subject line of the email.	
DATERCVD	Date and time that an email was received.	mm/dd/yyyy, yyyy/mm/dd, or yyyymmdd; hh:mm:ss AM/PM or hh:mm:ss
DATESENT	Date and time that an email was sent.	mm/dd/yyyy, yyyy/mm/dd, or yyyymmdd; hh:mm:ss AM/PM or hh:mm:ss
CALBEGDATE	Date that a meeting begins.	mm/dd/yyyy, yyyy/mm/dd, or yyyymmdd; hh:mm:ss AM/PM or hh:mm:ss
CALENDDATE	Date that a meeting ends.	mm/dd/yyyy, yyyy/mm/dd, or yyyymmdd; hh:mm:ss AM/PM or hh:mm:ss
ATTACHMENTS	List of filenames of all attachments, delimited by ";" when field has multiple values.	AttachmentFileName.; AttachmentFileName.docx; AttachmentFileName.pdf;…
NUMATTACH	Number of attachments.	
RECORDTYPE	General type of record.	IMAGE; LOOSE E-MAIL; E-MAIL; E-DOC; IMAGE ATTACHMENT; LOOSE E-MAIL ATTACHMENT; E-MAIL ATTACHMENT; E-DOC ATTACHMENT
FOLDERLOC	Original folder path of the produced document.	Drive:\Folder\...\...\
FILENAME	Original filename of the produced document.	Filename.ext
DOCEXT	Original file extension.	html, xls, pdf
DOCTYPE	Name of the program that created the produced document.	Adobe Acrobat, Microsoft Word, Microsoft Excel, Corel WordPerfect…
TITLE	Document title (if entered).	
AUTHOR	Name of the document author.	
REVISION	Number of revisions to a document.	18

DATECREATED	Date and time that a document was created.	mm/dd/yyyy, yyyy/mm/dd, or yyyymmdd; hh:mm:ss AM/PM or hh:mm:ss
DATEMOD	Date and time that a document was last modified.	mm/dd/yyyy, yyyy/mm/dd, or yyyymmdd; hh:mm:ss AM/PM or hh:mm:ss
FILESIZE	Original file size in bytes.	
PGCOUNT	Number of pages per document.	
IMPORTANCE	Email priority level if set.	Low, Normal, High
MD5HASH	MD5 hash value computed from native file (a/k/a file fingerprint).	
SHA1HASH	SHA1 hash value	
MSGINDEX	Email message ID	
CONVERSATIONINDEX	Email Conversation Index	

ATTACHMENT C

CERTIFICATION OF RECORDS OF REGULARLY CONDUCTED ACTIVITY
Pursuant to 28 U.S.C. § 1746

1. I, _____, have personal knowledge of the facts set forth below and am competent to testify as follows:

2. I have authority to certify the authenticity of the records produced by Georgetown Economic Services, LLC (the "Company") and attached hereto.

3. The documents produced and attached hereto by the Company are originals or true copies of records of regularly conducted activity that:

   a) Were made at or near the time of the occurrence of the matters set forth by, or from information transmitted by, a person with knowledge of those matters;

   b) Were kept in the course of the regularly conducted activity of the Company; and

   c) Were made by the regularly conducted activity as a regular practice of the Company.

I certify under penalty of perjury that the foregoing is true and correct.

Date: _____ _____
Signature

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, et. al. Plaintiffs, v. QUINCY BIOSCIENCE HOLDING COMPANY, INC., et. al Defendants.	Case No. 1:17-cv-00124-LLS

NON-PARTY GEORGETOWN ECONOMIC SERVICES, LLC'S OBJECTIONS AND REPONSES TO FEDERAL TRADE COMMISSION'S SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS

Non-party Georgetown Economic Services, LLC ("GES"), by and through its undersigned counsel, Kelley Drye & Warren LLP, hereby respectfully objects and responds to the Federal Trade Commission's ("FTC" or "Plaintiff") December 11, 2019 Subpoena to Produce Documents, Information, or Objects (the "Subpoena").

GENERAL OBJECTIONS AND RESERVATIONS OF RIGHTS

1. GES objects to the Subpoena, including the definitions contained therein, to the extent it seeks the production of materials protected from disclosure by the attorney-client privilege and the attorney work product doctrine including, but not limited to, protection under Rule 26(b)(4)(D) of the Federal Rules of Civil Procedure. GES was retained as a consulting expert in connection with an attempt to resolve this dispute with the FTC and is not expected at this time to be called as a witness in any trial of this action; therefore all documents and information in the possession of GES are protected from disclosure.

2. GES objects to the definition of "Defendants" in the Subpoena to the extent it includes unspecified individuals and entities who are not parties to this action.

3. GES objects to the definition of the "Madison Memory Study" in the Subpoena to the extent it suggests that the Madison Memory Study: (1) was conducted by unspecified individuals and entities who are not parties to this action; and (2) "includes any analysis of data or results conducted by Georgetown Economic Services, LLC or Dr. J. Howard Beales, III." As such, it is vague and overbroad.

4. Any inadvertent production of any document, material or other information shall not be deemed or construed to constitute a waiver of any privilege or right, and GES reserves the right to demand that FTC return any such document, material or other information and all copies thereof.

5. GES objects to the Subpoena to the extent it seeks the production of documents or information of a confidential or proprietary nature, or which constitute trade secrets.

6. GES objects to the Subpoena to the extent it is overly broad and unduly burdensome as it potentially calls for the production of irrelevant material.

7. GES objects to the Subpoena to the extent it requires the production of documents that are available to FTC from other sources. Therefore, the Subpoena is unreasonable because it imposes on GES, a third party, the burden of compiling and producing documents that are otherwise available to FTC.

8. These objections shall not be deemed or construed to suggest that there are, in fact, documents responsive to the Subpoena in GES's possession, custody or control.

SPECIFIC OBJECTIONS AND RESPONSES

The General Objections and Reservations of Rights stated above apply to and are incorporated into each of Quincy's responses to the Requests in the Subpoena as set forth below. Quincy objects and responds to the Requests in the Subpoena as follows:

REQUEST 1:

All documents concerning the scope of work to be performed, services to be provided, or compensation to be provided for work performed by the Company with regard to the Madison Memory Study.

OBJECTIONS AND RESPONSE TO REQUEST 1:

GES objects to this Request, including the definitions contained therein, to the extent it seeks the production of materials protected from disclosure by the attorney-client privilege and the attorney work product doctrine including, but not limited to, protection under Rule 26(b)(4)(D) of the Federal Rules of Civil Procedure. GES was retained as a consulting expert in connection with an attempt to resolve this dispute with the FTC and is not expected at this time to be called as a witness in any trial of this action. Therefore any responsive documents and information in the possession of GES are protected from disclosure. GES also objects to this Request as being overly broad in that it improperly defines the Madison Memory Study to include "any analysis of data or results conducted by Georgetown Economic Services, LLC or Dr. J. Howard Beales, III." GES also objects to this Request as being overly broad, unduly burdensome and disproportionate to the needs of this action insofar as the Request seeks documents that are irrelevant or that may be available to the FTC through party discovery.

GES will not produce documents in response to this Request.

REQUEST 2:

Concerning the Madison Memory Study, all documents concerning any statistical analysis of any data, including but not limited to any pretest analysis, intent-to-treat analysis, within-group analysis, subgroup analysis, supra-group analysis, re-analysis, post-hoc analysis, or seemingly unrelated regression (SUR) analysis, including but not limited to:

a. All reports, summaries, articles, write-ups, posters, presentations, data tables, or other accounts of the results of such analyses, and drafts of such documents reviewed by Defendants or any other individual or entity;
b. All documents relating to randomization; instructions, including but not limited to oral instructions to participants; subject compliance; dropouts; or dropout rates;

c. All statistical analysis plans, clinical agreements, reports, manuscripts, presentations, abstracts, or meeting notes or minutes, including any amendments, prepared by any individual or entity;
d. All draft, interim, or final data summaries, whether in chart, table, or any other form, including but not limited to baseline and outcome measurements for all enrolled subjects;
e. All data collected from enrolled participants, including but not limited to any participants who did not complete the Madison Memory Study; source documents for such data; and any case report forms;
f. All documents concerning collection and coding of the results of all tests administered on each subject; and
g. All other documents not explicitly referenced herein used to analyze or present the results of the Madison Memory Study.

OBJECTIONS AND RESPONSE TO REQUEST 2:

GES objects to this Request, including the definitions contained therein, to the extent it seeks the production of materials protected from disclosure by the attorney-client privilege and the attorney work product doctrine including, but not limited to, protection under Rule 26(b)(4)(D) of the Federal Rules of Civil Procedure. GES was retained as a consulting expert in connection with an attempt to resolve this dispute with the FTC and is not expected at this time to be called as a witness in any trial of this action. Therefore any responsive documents and information in the possession of GES are protected from disclosure. GES also objects to this Request as being overly broad in that it improperly defines the Madison Memory Study to include "any analysis of data or results conducted by Georgetown Economic Services, LLC or Dr. J. Howard Beales, III." GES also objects to this Request as being overly broad, unduly burdensome and disproportionate to the needs of this action insofar as the Request seeks documents that may be available to the FTC through party discovery. GES also objects to this Request as being overly broad, vague and ambiguous to the extent it seeks the production of documents that were "reviewed by Defendants or any other individual or entity." GES has no way of knowing whether documents were reviewed by Defendants (which is defined to include the named defendants in this action as well as

unspecified individuals and entities who are not party to this action) or any other individual or entity. GES objects to this Request to the extent it seeks the production of documents or information of a confidential or proprietary nature, or which constitute trade secrets.

GES will not produce documents in response to this Request.

REQUEST 3:

Concerning the Madison Memory Study, all documents related to the design, protocol, and recruitment of subjects, including but not limited to any documents evidencing any inclusion or exclusion criteria for participation in the study, whether related to subjects' AD-8 scores or otherwise.

OBJECTIONS AND RESPONSE TO REQUEST 3:

GES objects to this Request, including the definitions contained therein, to the extent it seeks the production of materials protected from disclosure by the attorney-client privilege and the attorney work product doctrine including, but not limited to, protection under Rule 26(b)(4)(D) of the Federal Rules of Civil Procedure. GES was retained as a consulting expert in connection with an attempt to resolve this dispute with the FTC and is not expected at this time to be called as a witness in any trial of this action. Therefore any responsive documents and information in the possession of GES are protected from disclosure. GES also objects to this Request as being overly broad in that it improperly defines the Madison Memory Study to include "any analysis of data or results conducted by Georgetown Economic Services, LLC or Dr. J. Howard Beales, III." GES also objects to this Request as being overly broad, unduly burdensome and disproportionate to the needs of this action insofar as the Request seeks documents that may be available to the FTC through party discovery. GES also objects to this Request to the extent it seeks the production of documents or information of a confidential or proprietary nature, or which constitute trade secrets.

GES will not produce documents in response to this Request.

REQUEST 4:

All communications with any outside entity or persons concerning the Madison Memory Study (including but not limited to any analyses of results or data of such study), including but not limited to communications with:

a. Any Defendant;
b. Michael Beaman;
c. CogState Ltd.;
d. Any person retained by, consulted by, or working with any Defendant, including but not limited to:
    i. Dr. J. Howard Beales, III;
    ii. Dr. David L. Katz;
    iii. Dr. Josh Levitt;
    iv. Dr. Mindy S. Kurzer;
    v. Dr. David H. Schwarz;
    vi. Dr. Giovanni Ciavarri;
    vii. Dr. Dominik Alexander;
    viii. Dr. Robert Krikorian;
    ix. Dr. Cedric Annweiler;
    x. Dr. Paul B. Pencharz;
    xi. Dr. Richard E. Goodman;
    xii. Dr. Michael Pezzone;
    xiii. Dr. Brian Spencer; and
    xiv. Dr. William Bisordi

OBJECTIONS AND RESPONSE TO REQUEST 4:

GES objects to this Request, including the definitions contained therein, to the extent it seeks the production of materials protected from disclosure by the attorney-client privilege and the attorney work product doctrine including, but not limited to, protection under Rule 26(b)(4)(D) of the Federal Rules of Civil Procedure. GES was retained as a consulting expert in connection with an attempt to resolve this dispute with the FTC and is not expected at this time to be called as a witness in any trial of this action. Therefore any responsive documents and information in the possession of GES are protected from disclosure. GES also objects to this Request as being overly broad in that it improperly defines the Madison Memory Study to include "any analysis of data or results conducted by Georgetown Economic Services, LLC or Dr. J. Howard Beales, III." GES also objects to this Request as being overly broad, vague and ambiguous to the extent it seeks the

production of communications with "Defendants," which is defined to include the named defendants in this action as well as unspecified individuals and entities who are not party to this action. GES also objects to this Request as being overly broad, vague and ambiguous to the extent it seeks the production of communications with "[a]ny person retained by, consulted by, or working with any Defendant." GES has no way of knowing whether an individual or entity has been retained by, consulted by, or is working with any of the named or unspecified "Defendants." GES also objects to this Request to the extent it seeks the production of documents or information of a confidential or proprietary nature, or which constitute trade secrets. GES also objects to this Request as being overly broad, unduly burdensome and disproportionate to the needs of this action insofar as the Request seeks documents that are irrelevant or that may be available to the FTC through party discovery.

GES will not produce documents in response to this Request.

REQUEST 5:

All documents relating to any other human clinical study commenced, discontinued, or completed by or on behalf of any Defendant involving apoaequorin or any product containing apoaequorin, including but not limited to any analysis of any data or results from any such study.

OBJECTIONS AND RESPONSE TO REQUEST 5:

GES objects to this Request to the extent it seeks the production of materials protected from disclosure by the attorney-client privilege and the attorney work product doctrine including, but not limited to, protection under Rule 26(b)(4)(D) of the Federal Rules of Civil Procedure. GES was retained as a consulting expert in connection with an attempt to resolve this dispute with the FTC and is not expected at this time to be called as a witness in any trial of this action. Therefore any responsive documents and information in the possession of GES are protected from disclosure. GES also objects to this Request as being overly broad, unduly burdensome and disproportionate

to the needs of this action insofar as the Request seeks documents that may be available to the FTC through party discovery. GES also objects to this Request to the extent it seeks the production of documents or information of a confidential or proprietary nature, or which constitute trade secrets.

GES will not produce documents in response to this Request.

Dated: New York, New York
December 26, 2019

KELLEY DRYE & WARREN LLP

By: */s/ Geoffrey W. Castello*

John E. Villafranco (admitted *pro hac vice*)
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Counsel for Non-Party Georgetown Economic Services, LLC

CERTIFICATE OF SERVICE

I hereby certify that on December 26, 2019, I caused the foregoing Non-Party Georgetown Economic Services, LLC's Objections and Responses to Federal Trade Commission's Subpoena to Produce Documents, Information or Objects by email upon the following parties and participants:

Michelle Rusk
Annette Soberats
Ed Glennon
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/s/ Jaclyn M. Metzinger
Jaclyn M. Metzinger